

DIGIRAD CORP  
Form 10-Q/A  
August 12, 2004

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 10-Q/A**

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(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2004**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_**

Commission file number: 000-50789

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**Digirad Corporation**

(Exact name of registrant as specified in its charter)

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**Delaware**

(State or other jurisdiction of incorporation or organization)

**33-0145723**

(IRS Employer Identification No)

**13950 Stowe Drive**

**Poway, California 92064**

(Address of principal executive offices)

**(858) 726-1600**

(Registrant's telephone number including area code)

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Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of July 31, 2004, the registrant had 18,011,316 shares of Common Stock (\$0.0001 par value) outstanding.

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Explanatory Note

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This Amendment No. 1 is being filed to include Exhibits 3.1 and 3.2 which were unintentionally omitted by the financial printer from the original filing. No other changes were made to this filing.

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## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

**Digirad Corporation**  
**Consolidated Balance Sheets**

	<b>June 30, 2004</b>	<b>December 31, 2003</b>
<b>Assets</b>	<b>(Unaudited)</b>	
<b>Current assets:</b>		
Cash and cash equivalents	\$ 60,394,364	\$ 7,681,407
Accounts receivable, net	10,589,908	12,195,031
Inventories, net	4,405,163	3,709,321
Other current assets	982,101	854,170
	76,371,536	24,439,929
Property and equipment, net	11,141,698	10,087,030
Intangibles, net	514,674	511,832
Restricted cash	120,000	120,000
	\$ 88,147,908	\$ 35,158,791
	\$ 88,147,908	\$ 35,158,791
 <b>Liabilities and stockholders equity (deficit)</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 4,525,581	\$ 3,036,209
Accrued compensation	2,119,839	1,893,336
Accrued warranty	1,268,535	1,051,242
Other accrued liabilities	4,190,275	2,647,741
Deferred revenue	2,036,744	1,514,488
Current portion of notes payable to stockholders	81,667	245,000
Current portion of debt	2,296,899	11,473,619
	16,519,540	21,861,635
Total current liabilities	16,519,540	21,861,635
Deferred rent	273,175	
Notes payable to stockholders, net of current portion	142,917	490,000
Long-term debt, net of current portion	3,246,570	4,232,071
Commitments and contingencies		
Redeemable convertible preferred stock, \$0.0001 par value:		
no shares and 46,023,000 shares authorized at June 30,		
2004 and December 31, 2003, respectively; no shares and		
43,555,313 shares issued and outstanding at June 30, 2004		
(unaudited) and December 31, 2003, respectively		84,277,992
 <b>Stockholders equity (deficit):</b>		
Preferred stock, \$0.0001 par value: 10,000,000 and no		
shares authorized at June 30, 2004 and December 31,		
2003, respectively; no shares issued and outstanding at		
June 30, 2004 and December 31, 2003, respectively		
Common stock, \$0.0001 par value: 150,000,000 and		
53,000,000 shares authorized at June 30, 2004 and		
December 31, 2003, respectively; 18,008,390 and 23,540		
shares issued and outstanding at June 30, 2004 (unaudited)		
and December 31, 2003, respectively	1,801	2
Additional paid-in capital	149,972,268	5,031,891

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Deferred compensation	(1,503,696)	(554,375)
Accumulated deficit	(80,504,667)	(80,180,425)
	<u>                    </u>	<u>                    </u>
Total stockholders' equity (deficit)	67,965,706	(75,702,907)
	<u>                    </u>	<u>                    </u>
Total liabilities and stockholders' equity (deficit)	\$ 88,147,908	\$ 35,158,791
	<u>                    </u>	<u>                    </u>

See accompanying notes.

**Digirad Corporation**  
**Consolidated Statements of Operations**  
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
<b>Revenues:</b>				
DIS	\$ 11,294,909	\$ 8,763,586	\$ 21,701,887	\$ 16,266,512
Product	5,995,129	5,248,687	11,456,015	10,724,978
<b>Total revenues</b>	<b>17,290,038</b>	<b>14,012,273</b>	<b>33,157,902</b>	<b>26,991,490</b>
<b>Cost of revenues:</b>				
DIS	7,509,457	6,087,476	14,774,023	11,729,380
Product	3,983,966	4,131,203	7,623,306	7,972,146
Stock-based compensation	130,510	29,812	246,006	31,129
<b>Total cost of revenues</b>	<b>11,623,933</b>	<b>10,248,491</b>	<b>22,643,335</b>	<b>19,732,655</b>
<b>Gross profit</b>	<b>5,666,105</b>	<b>3,763,782</b>	<b>10,514,567</b>	<b>7,258,835</b>
<b>Operating expenses:</b>				
Research and development	684,916	595,728	1,325,067	1,175,002
Sales and marketing	1,859,427	1,435,895	3,639,832	2,982,426
General and administrative	2,497,690	1,983,060	4,643,160	3,834,387
Amortization and impairment of intangible assets	16,076	94,409	32,152	213,658
Stock-based compensation	249,980	29,651	437,272	30,359
<b>Total operating expenses</b>	<b>5,308,089</b>	<b>4,138,743</b>	<b>10,077,483</b>	<b>8,235,832</b>
<b>Income (loss) from operations</b>	<b>358,016</b>	<b>(374,961)</b>	<b>437,084</b>	<b>(976,997)</b>
<b>Other income (expense):</b>				
Interest income	33,886	9,091	41,793	20,034
Interest expense	(289,458)	(429,430)	(612,042)	(765,161)
Other	200		(29,742)	
<b>Total other income (expense)</b>	<b>(255,372)</b>	<b>(420,339)</b>	<b>(599,991)</b>	<b>(745,127)</b>
<b>Net income (loss)</b>	<b>102,644</b>	<b>(795,300)</b>	<b>(162,907)</b>	<b>(1,722,124)</b>
Accretion of deferred issuance costs on preferred stock	(72,797)	(84,106)	(161,335)	(169,456)
<b>Net income (loss) applicable to common stockholders</b>	<b>\$ 29,847</b>	<b>\$ (879,406)</b>	<b>\$ (324,242)</b>	<b>\$ (1,891,580)</b>
<b>Net income (loss) per common share:</b>				
Basic (1)	\$ 0.01	\$ (63.08)	\$ (0.16)	\$ (137.67)
Diluted (1)	\$ 0.01	\$ (63.08)	\$ (0.16)	\$ (137.67)
<b>Shares used in computing net income (loss) per share:</b>				
Weighted average shares outstanding - Basic	4,002,598	13,942	2,017,564	13,740
Weighted average shares outstanding - Diluted	15,131,932	13,942	2,017,564	13,740

(1)

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As a result of the conversion of our preferred stock into 12.4 million shares of our common stock upon completion of our initial public offering in June 2004, there is a lack of comparability in the basic and diluted net income (loss) per share amounts for the periods presented above. Please refer to Note 8 for an unaudited pro forma basic and diluted net income (loss) per share calculation for the periods presented.

See accompanying notes.

**Digirad Corporation**  
**Consolidated Statements of Cash Flows**  
(Unaudited)

	Six months ended June 30,	
	2004	2003
<b>Operating activities</b>		
Net loss	\$ (162,907)	\$ (1,722,124)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	1,467,211	1,377,959
Loss on disposal of assets	29,742	764
Amortization and impairment of intangibles	32,152	213,658
Stock-based compensation	683,278	61,488
Changes in operating assets and liabilities:		
Accounts receivable	1,605,123	(2,524,777)
Inventories	(695,842)	2,001,386
Other assets	(97,781)	13,318
Accounts payable	1,489,372	780,062
Accrued compensation	226,503	(158,439)
Accrued warranty and other accrued liabilities	2,033,002	(618,393)
Deferred revenue	522,256	(62,646)
	7,132,109	(637,744)
<b>Investing activities</b>		
Purchases of property and equipment	(2,551,620)	(1,015,577)
Patents and other assets	(34,995)	(23,758)
	(2,586,615)	(1,039,335)
<b>Financing activities</b>		
Issuances of common stock, net of offering costs	58,840,100	837
Net borrowings (repayments) under lines of credit	(9,356,726)	1,146,266
Proceeds from capital lease financing	235,024	1,228,708
Repayment of obligations under capital leases	(1,040,519)	(913,958)
Repayment of notes payable to stockholders	(510,416)	
	48,167,463	1,461,853
Net increase (decrease) in cash and cash equivalents	52,712,957	(215,226)
Cash and cash equivalents at beginning of period	7,681,407	6,987,666
	\$ 60,394,364	\$ 6,772,440
<b>Supplemental information:</b>		
Cash paid during the period for interest	\$ 617,629	\$ 689,541

See accompanying notes.



## Digirad Corporation

Notes to Consolidated Financial Statements  
(unaudited)

## 1. Organization and Basis of Presentation

Digirad Corporation ( Digirad ), a Delaware corporation, designs, develops, manufactures, markets, and services solid-state digital gamma cameras for use in nuclear medicine and provides, through two subsidiaries, Digirad Imaging Solutions, Inc. and Digirad Imaging Systems, Inc., collectively DIS, in-office services for physicians, offering certified personnel, required licensure, an imaging system and other support for the performance of nuclear imaging procedures under the supervision of our physician customers. DIS physician customers enter into annual contracts for imaging services delivered on a per-day basis.

We have prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of our management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Intercompany accounts have been eliminated in consolidation. Operating results for the three and six months ended June 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. For further information see the financial statements and disclosures thereto for the year ended December 31, 2003 in our prospectus filed on June 9, 2004 and included in our Registration Statement filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on June 10, 2004.

## 2. Inventories

Inventories consist of the following:

	June 30, 2004	December 31, 2003
Raw materials	\$ 1,534,575	\$ 1,402,187
Work-in-progress	3,114,118	2,203,700
Finished goods	199,830	439,739
	4,848,523	4,045,626
Less reserves for excess and obsolete inventories	(443,360)	(336,305)
	\$ 4,405,163	\$ 3,709,321

## 3. Warranty

We provide a warranty on certain of our products and accrue the estimated cost at the time revenue is recorded. Warranty expense is charged to product cost of goods sold. Substantially all of the warranty periods are 12 months before customer-sponsored maintenance begins. Warranty reserves are established based on historical experience with failure rates and repair costs and the number of gamma cameras covered by warranty and are depleted as gamma cameras are repaired. The costs consist principally of materials, personnel, overhead and transportation. We review warranty reserves monthly and, if necessary, make adjustments.

The activities in our warranty reserve during the three months ended June 30, 2004 and 2003 are as follows:

	Balance at beginning of period	Charged to cost of revenues	Applied to liability	Balance at end of period
Three months ended June 30, 2004	\$ 1,176,537	\$ 474,000	\$ 382,002	\$ 1,268,535
Three months ended June 30, 2003	\$ 1,156,843	\$ 505,689	\$ 706,721	\$ 955,812



## Digirad Corporation

Notes to Consolidated Financial Statements  
(unaudited)

## 4. Debt

The composition of our debt balance is as follows:

	June 30, 2004	December 31, 2003
Lines of credit	\$ 5,543,469	\$ 9,356,727
Capital lease obligations	5,543,469	6,348,963
	5,543,469	15,705,690
Current portion of debt	(2,296,899)	(11,473,619)
Long-term debt, less current portion	\$ 3,246,570	\$ 4,232,071

*Lines of Credit*

In June 2004, we paid down both existing lines of credit to zero. We continue to have \$10,000,000 of available credit, subject to certain limitations. The available credit expires \$5,000,000 on October 15, 2004 and \$5,000,000 on December 31, 2004.

*Notes Payable to Stockholders*

On May 7, 2004, we agreed to accelerate payments due under certain notes payable to stockholders and to issue warrants to two of our stockholders and their designees following the consummation of our initial public offering. The warrants to purchase 47,618 shares of common stock were valued using the Black-Scholes option pricing model and the fair value of these warrants was \$355,000. The issuance of the warrants was directly attributable to completing our initial public offering and, therefore, is accounted for in stockholders' equity. We intend to enter into a similar agreement with an additional stockholder and its designees whereby we would issue warrants to purchase up to 23,809 shares of our common stock valued at approximately \$123,000.

## 5. Redeemable Convertible Preferred Stock and Stockholders' Equity

*Redeemable convertible preferred stock*

As part of the initial public offering completed in June 2004, all of our redeemable convertible preferred stock was converted into 12,444,271 shares of our common stock.

*Reverse stock split*

On April 30, 2004, our stockholders approved a 1-for-3.5 reverse stock split of our outstanding common stock. The accompanying consolidated financial statements give retroactive effect to the reverse stock split for all periods presented.

*Initial Public Offering*

In June 2004, we completed an initial public offering whereby we sold 5,500,000 shares of common stock at \$12 per share and received net proceeds of \$58.8 million (after underwriting discounts and commissions and estimated offering expenses).

*2004 Stock Incentive Plan*

Upon the effectiveness of the initial public offering, we adopted the 2004 Stock Incentive Plan and reserved 1,400,000 shares of common stock for issuance pursuant to the plan.

## Digirad Corporation

Notes to Consolidated Financial Statements  
(unaudited)

## 6. Commitments and Contingencies

*Compliance with Laws and Regulations*

We are directly, or indirectly through our clients, subject to extensive regulation by both the federal government and the states and foreign countries in which we conduct business. The healthcare laws applicable to us are complex and are subject to variable interpretations. We have established a compliance program to help ensure that we will remain in compliance with the applicable healthcare laws and have instituted other safeguards intended to help prevent any violations of the laws and to remedy any situations that could give rise to violations.

In the first quarter of 2004, we discovered certain isolated arrangements entered into in good faith but that, upon review by our compliance personnel, raised some compliance concerns under these laws. In accordance with our compliance program, we took immediate remedial steps. While there have been no claims asserted against us, we cannot assure you that those remedial steps will insulate us from liability associated with these isolated arrangements. Although uncertain, if a claim were asserted and we were not to prevail, possible sanctions could have a material effect on our financial statements or our ability to conduct our operations.

*Legal Matters*

We may from time to time become involved in litigation relating to claims arising in the normal course of business, such as claims related to customer disputes, employment practices, product liability or patent infringement. Currently, we are not involved in any litigation which could have a material adverse impact on our financial statements.

## 7. Stock-Based Compensation

We have elected to follow Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations in accounting for our employee stock options as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation*. Under APB 25, if the exercise price of our employee stock options is not less than the fair value of the underlying stock on the date of grant, no compensation expense is recognized. The following table illustrates the effect on net earnings and earnings per share as if we had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Net income (loss) per common share, as reported	\$ 29,847	\$ (879,406)	\$ (324,242)	\$ (1,891,580)
Add: total stock-based employee compensation included in reported net income (loss)	380,490	59,463	673,228	61,488
Less: total stock-based employee compensation determined under the fair value method for all awards	(435,921)	(62,239)	(766,021)	(77,681)
Pro forma net income (loss)	\$ (25,584)	\$ (882,182)	\$ (417,035)	\$ (1,907,773)
Net income (loss) per common share, as reported:				
Basic	\$ 0.01	\$ (63.08)	\$ (0.16)	\$ (137.67)
Diluted	\$ 0.01	\$ (63.08)	\$ (0.16)	\$ (137.67)
Net income (loss) per common share, pro forma:				
Basic	\$ (0.01)	\$ (63.28)	\$ (0.21)	\$ (138.85)
Diluted	\$ (0.01)	\$ (63.28)	\$ (0.21)	\$ (138.85)

The fair value of the options granted prior to the completion of our initial public offering were estimated at the date of grant using the minimum value pricing model. Upon completion of the initial public offering in June 2004, we began using the Black-Scholes model to estimate fair value. The estimated fair value of the options is amortized on an accelerated basis in accordance with FASB Interpretation ( FIN ) No. 28

over the vesting period.

## Digirad Corporation

Notes to Consolidated Financial Statements  
(unaudited)

The following assumptions were utilized for the calculations during each period:

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Expected dividend yield				
Risk-free interest rate	3.40%	3.00%	3.08%	3.00%
Expected volatility	%	%	%	%
Expected life (in years):	5.00	5.00	5.00	5.00

The above results are not likely to be representative of the effects of applying SFAS No.123 on reported net income or loss for future periods.

Stock-based compensation expense for stock options and warrants granted to non-employees is recorded at fair value as determined in accordance with SFAS No. 123, and EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Conjunction with Selling Goods or Services*. The fair value of the unvested options, warrants, and other equity instruments is periodically remeasured and the related expense is adjusted as necessary.

The composition of stock-based compensation is as follows:

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
The composition of stock-based compensation is as follows:				
Cost of DIS revenue	\$ 65,863	\$ 3,080	\$ 126,293	\$ 4,362
Cost of product revenue	64,647	26,732	119,713	26,767
Research and development	45,721	311	73,220	464
Sales and marketing	44,097	1,787	88,796	2,104
General and administrative	160,162	27,553	275,256	27,791
	<u>\$ 380,490</u>	<u>\$ 59,463</u>	<u>\$ 683,278</u>	<u>\$ 61,488</u>

## 8. Net Income (Loss) Per Share

We calculated net income (loss) per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic earnings per share (EPS) is calculated by dividing the net income or loss available to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net income available to common stockholders by the weighted average number of common shares outstanding for the period and the weighted average number of dilutive common stock equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by us, convertible preferred stock, options, and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

As mentioned above, upon the completion of our initial public offering, all of our previously outstanding preferred shares converted into 12.4 million shares of our common stock. As a result of the issuance of these common shares, there is a lack of comparability in both the basic and diluted net income (loss) per share amounts for the periods presented. In order to provide a more relevant measure of our operating results, an unaudited pro forma net income (loss) per share calculation has been included. The shares used to compute unaudited pro forma basic and diluted net income (loss) per share include the assumed conversion of all outstanding shares of preferred stock into shares of common stock using the as if converted method as of the beginning of each period presented or the date of issuance, if later.



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Digirad Corporation

Notes to Consolidated Financial Statements  
(unaudited)

Historical and pro forma basic and diluted net income (loss) per share were calculated as follows:

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
<b>Historical:</b>				
Numerator:				
Net income (loss) applicable to common stockholders - diluted	\$ 102,644	\$ (795,300)	\$ (162,907)	\$ (1,722,124)
Accretion of deferred issuance costs on preferred stock	(72,797)	(84,106)	(161,335)	(169,456)
Net income (loss) applicable to common stockholders - basic	\$ 29,847	\$ (879,406)	\$ (324,242)	\$ (1,891,580)
Denominator:				
Weighted average common shares outstanding - basic	4,002,598	13,942	2,017,564	13,740
Effect of dilutive securities:				
Conversion of preferred stock	9,709,266			
Options	1,397,374			
Warrants	22,694			
Weighted average common shares outstanding - diluted	15,131,932	13,942	2,017,564	13,740
Net income (loss) per common share:				
Basic	\$ 0.01	\$ (63.08)	\$ (0.16)	\$ (137.67)
Diluted	\$ 0.01	\$ (63.08)	\$ (0.16)	\$ (137.67)
<b>Pro forma:</b>				
Numerator:				
Net income (loss) applicable to common stockholders - basic and diluted	\$ 102,644	\$ (795,300)	\$ (162,907)	\$ (1,722,124)
Denominator:				
Weighted average common shares outstanding - basic	4,002,598	13,942	2,017,564	13,740
Pro forma adjustments to reflect weighted average effect of assumed conversion of preferred stock (unaudited)	9,709,266	12,444,271	11,076,769	12,444,271
Pro forma weighted average common shares outstanding - basic	13,711,864	12,458,213	13,094,333	12,458,011
Weighted average common shares outstanding - diluted	15,131,932	13,942	2,017,564	13,740
Pro forma adjustments to reflect weighted average effect of assumed conversion of preferred stock (unaudited)		12,444,271	11,076,769	12,444,271
Pro forma weighted average common shares outstanding - diluted	15,131,932	12,458,213	13,094,333	12,458,011



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	Three months ended June 30,		Six months ended June 30,	
Pro forma net income (loss) per common share:				
Basic	\$ 0.01	\$ (0.06)	\$ (0.01)	\$ (0.14)
Diluted	\$ 0.01	\$ (0.06)	\$ (0.01)	\$ (0.14)

## Digirad Corporation

Notes to Consolidated Financial Statements  
(unaudited)

## 9. Segments

We have determined our reporting segments based on the nature of the products and/or services offered to customers or the nature of their function in the organization. We evaluate performance based on the operating income contributed by each segment. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies.

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
<b>Gross profit by segment:</b>				
DIS	\$ 3,719,588	\$ 2,673,030	\$ 6,801,570	\$ 4,532,770
Product	1,946,517	1,090,752	3,712,997	2,726,065
Consolidated gross profit	\$ 5,666,105	\$ 3,763,782	\$ 10,514,567	\$ 7,258,835
<b>Income (loss) from operations by segment:</b>				
DIS	\$ 942,615	\$ 559,127	\$ 1,453,313	\$ 301,737
Product	(584,599)	(934,088)	(1,016,229)	(1,278,734)
Consolidated income (loss) from operations	\$ 358,016	\$ (374,961)	\$ 437,084	\$ (976,997)
<b>Depreciation, amortization and impairment of intangible assets by segment:</b>				
DIS	\$ 532,222	\$ 525,406	\$ 1,032,763	\$ 1,058,989
Product	231,259	261,206	466,600	532,628
Consolidated depreciation and amortization	\$ 763,481	\$ 786,612	\$ 1,499,363	\$ 1,591,617
<b>Identifiable assets by segment:</b>				
DIS	\$ 16,560,477	\$ 17,006,928	\$ 16,560,477	\$ 17,006,928
Product	71,587,431	15,854,112	71,587,431	15,854,112
Consolidated assets	\$ 88,147,908	\$ 32,861,040	\$ 88,147,908	\$ 32,861,040

Foreign sales have not been significant for any period presented.

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**  
**Forward-Looking Statements May Prove Inaccurate**

*The following discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2003 included in our Prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on June 10, 2004. Operating results are not necessarily indicative of results that may occur in future periods.*

*This report includes various forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results could differ materially from those anticipated in these forward looking statements as a result of various factors, including those set forth below under the caption Risk Factors. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, discussions regarding our operating strategy, growth strategy, acquisition strategy, cost savings initiatives, industry, economic conditions, financial condition, liquidity and capital resources and results of operations. In this report, for example, we make forward-looking statements regarding our expectations about the rate of revenue growth in specific business segments and the reasons for that growth and our profitability. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words believes, expects, anticipates, intends, estimates, projects, can, could, may, will, would, or similar expressions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not unduly rely on these forward-looking statements, which speak only as of the date on which they were made. They give our expectations regarding the future but are not guarantees. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.*

**Overview**

We are a leader in the development, manufacture and distribution of solid-state medical imaging products and services. We were the first company to develop and commercialize a solid-state medical gamma camera for the detection of cardiovascular disease and other medical conditions. Our high performance imaging systems are mobile and provide enhanced operability and reliability and improved patient comfort and utilization when compared to traditional vacuum tube cameras. The cameras and accompanying equipment fit easily into spaces as small as seven feet by eight feet and facilitate the delivery of nuclear medicine procedures directly in a physician's office, an outpatient hospital setting or within multiple departments of a hospital.

Our revenues are divided between two primary operating segments: our DIS business and product sales. DIS collectively refers to our wholly-owned subsidiaries, Digirad Imaging Solutions, Inc. and Digirad Imaging Systems, Inc. Through DIS, we offer FlexImaging, our mobile and comprehensive leasing service for physicians who wish to perform nuclear cardiology and nuclear medicine procedures in their offices, but do not have the patient volume, capital or personnel to justify purchasing an imaging system. DIS is currently provided in 18 states and the District of Columbia. Physicians enter into annual contracts for imaging services delivered on a per-day basis. Our annual lease contracts typically provide for one day of service per week. Our product revenue results primarily from selling solid-state gamma cameras, custom designed chairs and accessories, such as printers, viewing workstations and connectivity, and revenue from our maintenance contracts. We sell our imaging systems to physician practices, outpatient clinics and hospitals primarily in the United States, although we have sold a small number of imaging systems internationally.

Given the recurring contractual revenue stream from our DIS business and our strategy to continue to expand the number of areas where we offer DIS services, we expect DIS revenue to continue to grow at a higher rate than product revenue and to continue to represent the majority of our consolidated revenues. We attribute the overall growth of our business to geographical expansion, increased market penetration, awareness and acceptance of our services and products, and the shift in the delivery of nuclear cardiology imaging procedures from hospitals to physician offices. We believe that the increase in demand for our services and products is driven by the desire of cardiologists to control their patients diagnosis and treatment and to capture revenue for services that would otherwise be performed by a hospital or imaging center. The mobile feature of our technology also provides us with a significant advantage in the delivery of nuclear cardiology imaging services.

In April 2004, we completed the transition of our product manufacturing and headquarters operations from several separate facilities to a single facility in Poway, California. We believe that this consolidation will streamline our operations and improve efficiencies.

We experience some seasonality in our DIS business as a result of holidays, inclement weather and summer slowdowns principally relating to vacations. Historically, these variables have had the most impact on our third quarter operating results. As of June 30, 2004, our accumulated deficit was \$80.5 million. We believe that we will achieve our first full year of profitability in 2004, and intend to continue to enhance profitability through increased volume and improved margins, although we may incur losses in any given quarter. We also currently purchase some components from sole source providers but are either qualifying or seeking second source providers in an effort to limit our reliance on these suppliers.



**Results Of Operations**

The following table sets forth our results from operations, expressed as percentages of revenues for the three and six months ended June 30, 2004 and 2003:

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
<b>Revenues:</b>				
DIS	65.3%	62.5%	65.5%	60.3%
Product	34.7	37.5	34.5	39.7
Total revenues	100.0	100.0	100.0	100.0
<b>Cost of revenues:</b>				
DIS	43.4	43.4	44.6	43.5
Product	23.0	29.5	23.0	29.5
Stock-based compensation	0.8	0.2	0.7	0.1
Total cost of revenues	67.2	73.1	68.3	73.1
Gross profit	32.8	26.9	31.7	26.9
<b>Operating expenses:</b>				
Research and development	4.0	4.3	4.0	4.4
Sales and marketing	10.8	10.2	11.0	11.0
General and administrative	14.4	14.2	14.0	14.2
Amortization and impairment of intangible assets	0.1	0.7	0.1	0.8
Stock-based compensation	1.4	0.2	1.3	0.1
Total operating expenses	30.7	29.6	30.4	30.5
Income (loss) from operations	2.1	(2.7)	1.3	(3.6)
Other income (expense)	(1.5)	(3.0)	1.8	(2.7)
Accretion of deferred issuance costs on preferred stock	(0.4)	(0.6)	(0.5)	(0.6)
Net income (loss) applicable to common stockholders	0.2%	(6.3)%	(1.0)%	(6.9)%

**Comparison of Three Months Ended June 30, 2004 and 2003****Revenues**

*Consolidated.* Consolidated revenues increased to \$17.3 million for the three months ended June 30, 2004 from \$14.0 million for the three months ended June 30, 2003, which represents an increase of \$3.3 million, or 23.4%, primarily as a result of increased demand for our DIS imaging services. We believe that this increased demand was principally a result of increased customer awareness and acceptance of our products and services. DIS and product revenue accounted for 65% and 35%, respectively, of total revenues for the three months ended June 30, 2004, compared to 63% and 37%, respectively, for the three months ended June 30, 2003. We expect DIS revenue to continue to grow at a higher rate than product revenue and to continue to represent a larger percentage of consolidated revenue.

*DIS.* Our DIS revenue increased to \$11.3 million for the three months ended June 30, 2004 from \$8.8 million for the three months ended June 30, 2003, which represented an increase of \$2.5 million, or 28.9%. The increase in DIS revenue resulted from an increase in the number of DIS service days to 2,965 for the three months ended June 30, 2004 from 2,501 for the three months ended June 30, 2003, which was primarily attributable to an increase in the number of physicians entering into our DIS services contracts and growth of existing accounts. Our DIS business operated 63 imaging systems as of June 30, 2004 as compared to 51 as of June 30, 2003. We anticipate that our DIS revenue will increase as we expand into new markets and continue to penetrate existing markets. Such growth will fluctuate, however, based on seasonality stemming from physician vacations, holidays and inclement weather.

*Product.* Our product revenue increased to \$6.0 million for the three months ended June 30, 2004 from \$5.2 million for the three months ended June 30, 2003, which represented an increase of \$0.7 million, or 14.2%. The increase in product revenues resulted from an increase in

camera and accessories revenue as well as increased service contract revenues. We have experienced pricing pressures on our dual head gamma cameras and, while we expect this pricing pressure to continue, we also anticipate demand will continue to increase, potentially offsetting the effects of these pricing pressures.

*Gross Profit*

*Consolidated.* Consolidated gross profit increased to \$5.7 million for the three months ended June 30, 2004 from \$3.8 million for the three months ended June 30, 2003, which represents an increase of \$1.9 million, or 50.5%. Consolidated gross profit as a percentage of revenue increased to 32.8% for the three months ended June 30, 2004 from 26.9% for the three months ended June 30, 2003, primarily as a result of an increase in revenue, lower DIS imaging service costs and reductions in gamma camera production costs and per unit warranty costs.

*DIS.* Cost of DIS revenue consists primarily of labor, radiopharmaceuticals, equipment depreciation and other costs associated with the provision of services. Cost of DIS revenue increased to \$7.5 million for the three months ended June 30, 2004 from \$6.1 million for the three months ended June 30, 2003, which represents an increase of \$1.4 million, or 23.4%, primarily as a result of an increase in our direct headcount and consumables used in performing imaging services, which are primarily radiopharmaceuticals. Our clinical headcount relating to our DIS business increased to 155 employees at June 30, 2004 from 120 employees at June 30, 2003. DIS gross profit increased to \$3.8 million for the three months ended June 30, 2004 from \$2.7 million for the three months ended June 30, 2003, which represents an increase of \$1.1 million, or 41.5%, as a result of increased volumes and reductions in the per unit cost of labor and radiopharmaceuticals used in providing our imaging services. DIS gross profit as a percentage of revenue increased to 33.5% for the three months ended June 30, 2004 from 30.5% for the three months ended June 30, 2003.

*Product.* Cost of goods sold primarily consists of materials, labor and overhead costs associated with the manufacturing and warranty of our products. Warranty costs are charged to cost of goods sold in the period our cameras are sold and are based on our historical experience with failure rates and repair costs. Warranty reserves are reviewed monthly and if necessary, warranty expense is adjusted. Cost of goods sold decreased to \$4.0 million for the three months ended June 30, 2004 from \$4.1 million for the three months ended June 30, 2003, which represents a decrease of \$0.1 million, or 3.6%. Product gross profit increased to \$2.0 million for the three months ended June 30, 2004 from \$1.1 million for the three months ended June 30, 2003, which represents an increase of \$0.9 million, or 80.0%, primarily as a result of the decrease in cost of goods sold and reduced costs per unit resulting from lower warranty costs, increased manufacturing volumes, fewer and lower-cost materials and more efficient manufacturing processes used to build our third-generation camera heads introduced in July 2003. Product gross profit as a percentage of revenue increased to 33.5% for the three months ended June 30, 2004 from 21.3% for the three months ended June 30, 2003.

*Operating Expenses*

*Research and Development.* Research and development expenses consist primarily of costs associated with the design, development, testing, and enhancement of our products. The primary costs are salaries and fringe benefits, consulting fees, facilities and overhead charges and nonrecurring engineering costs, such as tooling and other one-time costs associated with manufacturing. Research and development expenses increased to \$0.7 million for the three months ended June 30, 2004 from \$0.6 million for the three months ended June 30, 2003, which represents an increase of \$0.1 million, or 15.0%. This increase was primarily attributable to increased employee headcount to develop new products. For the three months ended June 30, 2004, research and development expenses were 4.0% of total revenue, compared to 4.3% for the three months ended June 30, 2003. In the future, we expect to continue to invest between approximately 10% and 12% of product revenue on research and development as we seek to continue to improve our existing technology and innovate.

*Sales and Marketing.* Sales and marketing expenses consist primarily of salaries, commissions, bonuses, recruiting costs, travel, marketing and collateral materials and tradeshow costs. Sales and marketing expenses increased to \$1.9 million for the three months ended June 30, 2004, from \$1.4 million for the three months ended June 30, 2003, which represents an increase of \$0.4 million, or 29.5%. This increase was primarily attributable to an increase in the number of sales and marketing personnel and expansion of our marketing efforts. For the three months ended June 30, 2004, sales and marketing expenses were 10.8% of total revenue, compared to 10.2% for the three months ended June 30, 2003. We expect to increase our sales and marketing efforts, as we expand the locations in which we expect to perform DIS services and focus on increasing market awareness of our products and offerings.

*General and Administrative.* General and administrative expenses consist primarily of salaries and other related costs for finance and accounting, human resources and other personnel, as well as legal and other professional fees and insurance. General and administrative expenses increased to \$2.5 million for the three months ended June 30, 2004 from \$2.0 million for the three months ended June 30, 2003, which represents an increase of \$0.5 million, or 26.0%. Increases in headcount and recruiting costs, and insurance, legal fees and other costs primarily related to our IPO and operating as a newly public company, and DIS billing and collection fees, all contributed to increased general and administrative expenses. At the end of June 30, 2004, general and administrative expenses amounted to 14.4% of total revenue compared to 14.2% at the end of June 30, 2003. As a result of our initial public offering, we will be required to incur additional general and administrative costs to meet various public reporting and compliance requirements.

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**Stock-Based Compensation Charges.** Deferred compensation for stock options granted to employees has been determined as the difference between the exercise price and the fair value of our common stock on the date of grant. Options or awards issued to non-employees are recorded at their fair value in accordance with SFAS No. 123 and periodically remeasured in accordance with EITF 96-18 and recognized over the respective service or vesting period. These amounts are initially recorded as a component of stockholders' equity and are amortized, on an accelerated basis, as a non-cash charge to cost of revenues and operations over the vesting period of the options. In connection with the grant of stock options to employees, we recorded amortization of stock-based compensation of \$0.4 million and \$0.1 million for the three months ended June 30, 2004 and 2003, respectively.

### *Other Income (Expense)*

Interest expense decreased to \$0.3 million for the three months ended June 30, 2004 from \$0.4 million for the three months ended June 30, 2003, which represents a decrease of \$0.1 million, or 32.6%. The reduction is a result of a decrease in the variable interest rates on two accounts receivable credit lines and a reduction on capital leases.

### *Net Income (Loss)*

Net income increased to \$0.1 million for the three months ended June 30, 2004 from a net loss of \$0.8 million for the three months ended June 30, 2003, as a result of the factors described above.

### **Comparison of Six Months Ended June 30, 2004 and 2003**

#### *Revenues*

**Consolidated.** Consolidated revenues increased to \$33.2 million for the six months ended June 30, 2004 from \$27.0 million for the six months ended June 30, 2003, which represents an increase of \$6.2 million, or 22.8%, primarily as a result of increased demand for our DIS imaging services. We believe that this increased demand was principally a result of increased customer awareness and acceptance of our products and services. DIS and product revenue accounted for 66% and 34%, respectively, of total revenues for the six months ended June 30, 2004, compared to 60% and 40%, respectively, for the six months ended June 30, 2003. We expect DIS revenue to continue to grow at a higher rate than product revenue and to continue to represent a larger percentage of consolidated revenue.

**DIS.** Our DIS revenue increased to \$21.7 million for the six months ended June 30, 2004 from \$16.3 million for the six months ended June 30, 2003, which represents an increase of \$5.4 million, or 33.4%. The increase in DIS revenue resulted from an increase in the number of DIS service days to 5,699 for the six months ended June 30, 2004 from 4,511 for the three months ended June 30, 2003, which was primarily attributable to an increase in the number of physicians entering into our DIS services contracts, growth of existing accounts and the deployment of additional mobile imaging systems. Our DIS business operated 63 imaging systems as of June 30, 2004 as compared to 51 as of June 30, 2003.

**Product.** Our product revenue increased to \$11.5 million for the six months ended June 30, 2004 from \$10.7 million for the six months ended June 30, 2003, which represents an increase of \$0.7 million, or 6.8%. The increase in product revenues resulted from an increase in camera and accessories revenue as well as increased service contract revenues.

#### *Gross Profit*

**Consolidated.** Consolidated gross profit increased to \$10.5 million for the six months ended June 30, 2004 from \$7.3 million for the six months ended June 30, 2003, which represents an increase of \$3.3 million, or 44.9%. Consolidated gross profit as a percentage of revenue increased to 31.7% for the six months ended June 30, 2004 from 26.9% for the six months ended June 30, 2003, primarily as a result of an increase in revenue, lower DIS imaging service costs and reductions in gamma camera production costs and per unit warranty cost s.

**DIS.** Cost of DIS revenue increased to \$14.8 million for the six months ended June 30, 2004 from \$11.7 million for the six months ended June 30, 2003, which represents an increase of \$3.0 million, or 26.0%, primarily as a result of our increased direct headcount and consumables used in performing imaging services, which are primarily radiopharmaceuticals. Our clinical headcount relating to our DIS business increased to 155 employees at June 30, 2004 from 120 employees at June 30, 2003. DIS gross profit increased to \$6.9 million for the six months ended June 30, 2004 from \$4.5 million for the six months ended June 30, 2003, which represents an increase of \$2.4 million, or 52.7%, as a result of increased volumes and reductions in the per unit cost of labor and radiopharmaceuticals used in providing our imaging services. DIS gross profit as a percentage of revenue increased to 31.9% for the six months ended June 30, 2004 from 27.9% for the six months ended June 30, 2003.



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*Product.* Cost of goods sold decreased to \$7.6 million for the six months ended June 30, 2004 from \$8.0 million for the six months ended June 30, 2003, which represents a decrease of \$0.3, or 4.4%. Product gross profit increased to \$3.8 million for the six months ended June 30, 2004 from \$2.8 million for the six months ended June 30, 2003, which represents an increase of \$1.1million, or 39.2%, primarily as a result of the decrease in cost of goods sold and reduced costs per unit resulting from lower warranty costs, increased manufacturing volumes, fewer and lower-cost materials and more efficient manufacturing processes used to build our third-generation camera heads introduced in July 2003. Product gross profit as a percentage of revenue increased to 33.5% for the six months ended June 30, 2004 from 25.7% for the six months ended June 30, 2003.

### *Operating Expenses*

*Research and Development.* Research and development expenses increased to \$1.3 million for the six months ended June 30, 2004 from \$1.2 million for the six months ended June 30, 2003, which represents an increase of \$0.2 million, or 12.8%. This increase was primarily attributable to increased employee headcount to develop new products. For the six months ended June 30, 2004, research and development expenses were 4.0% of total revenue, compared to 4.4% for the six months ended June 30, 2003.

*Sales and Marketing.* Sales and marketing expenses increased to \$3.6 million for the six months ended June 30, 2004, from \$3.0 million for the six months ended June 30, 2003, which represents an increase of \$0.7 million, or 22.0%. This increase was primarily attributable to an increase in the number of sales and marketing personnel and expansion of our marketing efforts. Sales and marketing expenses were 11.0% of total revenue for both of the six month periods ended June 30, 2004 and 2003.

*General and Administrative.* General and administrative expenses increased to \$4.6 million for the six months ended June 30, 2004 from \$3.8 million for the six months ended June 30, 2003, which represents an increase of \$0.8 million, or 21.1%. Increases in headcount and recruiting costs, and insurance, legal fees and other costs primarily related to our IPO and operating as a newly public company, and DIS billing and collection fees, all contributed to increased general and administrative expenses. At the end of June 30, 2004, general and administrative expenses amounted to 14.0% of total revenue compared to 14.2% at the end of June 30, 2003.

*Stock-Based Compensation Charges.* In connection with the grant of stock options to employees, we recorded as amortization of stock-based compensation of \$0.7 million and \$0.1 million for the six months ended June 30, 2004 and 2003, respectively.

### *Other Income (Expense)*

Interest expense decreased to \$0.6 million for the six months ended June 30, 2004 from \$0.8 million for the six months ended June 30, 2003, which represents a decrease of \$0.2 million, or 20.0%. The reduction is a result of a decrease in the variable interest rates on our two credit lines and a reduction of amounts outstanding under capital leases.

### *Net Loss*

The net loss decreased to \$0.2 million for the six months ended June 30, 2004 from \$1.7 million for the six months ended June 30, 2003, as a result of the factors described above.

## **Liquidity and Capital Resources**

We require capital principally for working capital, debt service and capital expenditures. Working capital is required principally to finance accounts receivable and inventory. Our working capital requirements vary from period to period depending on manufacturing volumes, the timing of deliveries and the payment cycles of our customers. Our capital expenditures consist primarily of DIS cameras and vans, computer hardware and software. We have historically funded our operations principally through private placements of equity securities. In June 2004, we completed our initial public offering and received net proceeds of \$58.8 million.

As of June 30, 2004, we had cash and cash equivalents totaling \$60.4 million. We currently invest our cash reserves in money market funds. We also have two separate credit facilities that provide up to \$10.0 million of borrowing capacity, subject to certain limitations.

Net cash provided by operations was approximately \$7.1 million for the six months ended June 30, 2004. Net cash provided by operating activities for the six months ended June 30, 2004 was primarily the result of a decrease in accounts receivable and increases in accounts payable and accrued liabilities, augmented by non-cash items such as depreciation and amortization of stock-based compensation. The decrease in accounts receivable reflects a reduction in our days sales outstanding. The increase in accounts payable reflects the growth of our business while the increase in accrued liabilities is primarily associated with the accrual of costs associated with our initial public offering.

Net cash used in investing activities amounted to approximately \$2.6 million for the six months ended June 30, 2004, and reflects capital expenditures primarily associated with our DIS operations.



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Net cash provided by financing activities amounted to approximately \$48.2 million for the six months ended June 30, 2004. Proceeds from the initial public offering less amounts paid under credit line borrowings and capital lease obligations were primarily responsible for the net cash provided by financing activities in the six months ended June 30, 2004.

Based upon our current level of expenditures, we believe the proceeds from our initial public offering, together with cash flows from operating activities will be adequate to meet our anticipated cash requirements for working capital, debt service and capital expenditures for the next 12 months.

### **Critical Accounting Policies**

The Securities and Exchange Commission defines critical accounting policies as those that are, in management's opinion, very important to the portrayal of our financial condition and results of operations and require our management's most difficult, subjective or complex judgments. In preparing our financial statements in accordance with generally accepted accounting principles in the United States, we must often make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures at the date of the financial statements and during the reporting period. Some of those judgments can be subjective and complex. Consequently, actual results could differ from our estimates. The accounting policies that are most subject to important estimates or assumptions include those described below.

#### ***Revenue Recognition***

We recognize revenue in accordance with Staff Accounting Bulletin No. 101 when each of the following four criteria are met:

1. A contract or sales arrangement exists;
2. Products have been shipped and title has transferred or services have been rendered;
3. The price of the products or services is fixed or determinable; and
4. Collectibility is reasonably assured.

For our product revenue, these criteria are usually met upon delivery. Our DIS revenue is recorded once the services and disposables are provided and consumed, which is normally on the day of the service. Reductions to product revenue are recorded to provide for payment adjustments and credit memos and historically have not been significant. Reductions to our DIS revenue are recorded to provide for payment adjustments and credit memos. In addition, we establish reserves against our DIS revenue to allow for uncollectible items relating to patient co-payments and contractual allowances and other adjustments, based on historical collection experience.

#### ***Reserves for Doubtful Accounts, Billing Adjustments and Contractual Allowances***

Historically, the need to estimate reserves for accounts receivable has been limited to our DIS business. We provide reserves for billing adjustments, contractual allowances and doubtful accounts. DIS payment adjustments and credit memos are adjustments for billing errors that are normally adjusted within the first 90 days subsequent to the performance of service, with the majority occurring within the first 30 days. Reserves are provided as a percentage of DIS revenue based on historical experience rate. We primarily bill the physicians under contract directly, and in a minority of cases, we are reimbursed under government programs, Medicare or by private insurance companies. We provide reserves for contractual allowances for billings to Medicare and insurance companies based on our collection experience rates. We use a combination of factors in evaluating the collectibility of accounts receivable. Each account is reviewed on at least a quarterly basis and a percentage varying from zero to 100% for each account is established. We do not establish reserves for accounts with a history of payment without disputes. We generally reserve between 20% and 50% of the outstanding balance for accounts that are more than 180 days late and under dispute. We reserve 100% of the outstanding balance for accounts that we believe constitute a high risk of default based on factors such as level of dispute, payment history and our knowledge of a customer's inability to meet its obligations. We also consider bad debt write-off history. Our estimates of collectibility could be reduced by material amounts by changed circumstances, such as a higher number of defaults or material adverse changes in a payor's ability to meet its obligations.

### **Long-Lived Assets**

We state property and equipment and purchased contracts at cost. We capitalize betterments, which extend the useful life of the equipment. We calculate depreciation on property and equipment and purchased contracts on the straight-line method over the estimated useful life (three to seven years for property and equipment and five years for purchased contracts) of the assets. We follow Financial Accounting Standards Board ( FASB ) *Statement of Financial Accounting Standards ( SFAS ) No. 144, Accounting for Impairment or Disposal of Long-Lived Assets*, which requires impairment losses to be recorded on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amount. If such assets are considered to be impaired, we measure the impairment to be recognized by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. Assets are examined for impairment annually or more frequently if events occur that may indicate potential asset impairment.

### **Inventory**

We state inventories at the lower of cost (first-in, first-out) or market (net realizable value). Costs include material, labor and manufacturing overhead costs. Inventory expected to be converted into equipment to be used as imaging cameras in DIS is classified as property and equipment. We review our inventory monthly for excess or obsolete inventory levels. Except where firm orders are on-hand, we consider inventory quantities of sale products in excess of the last 12 months' demand as excess and reserve for them at levels between 20% and 50% of cost, depending on our knowledge and forecast for the product. We establish obsolescence reserves from 0% for active, high-demand products, to 100% for obsolete products. We review the reserve periodically and, if necessary, make adjustments. We rely on historical information to support our reserve and utilize management's business judgment. Once the inventory is written down, we do not adjust the reserve balance until the inventory is sold.

### **Warranty**

We provide a warranty on certain of our products and accrue the estimated cost at the time revenue is recorded. Historically, the warranty periods have ranged from up to 24 months. Since July 2002, substantially all of the warranty periods have been 12 months before customer-sponsored maintenance begins. Warranty reserves are established based on historical experience with failure rates and repair costs and the number of cameras covered by warranty. We review warranty reserves monthly and, if necessary, make adjustments.

### **New Accounting Pronouncements**

In November 2002, the FASB issued FIN 45, *Guarantors' Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. This interpretation elaborates on the disclosures required in financial statements concerning obligations under certain guarantees. We adopted the disclosure requirements of this interpretation that were effective on December 31, 2002. The recognition provisions of the interpretation became effective in 2003 and are applicable only to guarantees issued or modified after December 31, 2002. We have not issued or modified any such guarantees and accordingly the interpretation did not have a material impact on our financial position, results of operations or cash flows.

In January 2003, the FASB issued FIN No. 46, *Consolidation of Variable Interest Entities*, an Interpretation of ARB No. 51. FIN No. 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. In December 2003, the FASB issued FIN No. 46R, a revision to FIN No. 46. FIN No. 46R provides a broad deferral of the latest date by which all public entities must apply FIN No. 46 to certain variable interest entities to the first reporting period ending after March 15, 2004. The adoption of FIN No. 46 or FIN No. 46R did not have a material impact upon our financial position, cash flows or results of operations.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have a material effect on our consolidated financial statements.

## Corporate Information

We have trademark registrations in the United States for 2020tc Imager<sup>®</sup>, CardiusSST<sup>®</sup>, Digirad<sup>®</sup>, Digirad Logo<sup>®</sup>, Digirad Imaging Solutions<sup>®</sup>, FlexImaging<sup>®</sup> and SPECTour<sup>®</sup>. We have trademark applications pending in the United States for the following marks: Cardius, DigiServ<sup>SM</sup>, DigiSpect<sup>SM</sup>, DigiTech<sup>SM</sup> and Solidium<sup>SM</sup>. We have obtained and sought trademark protection for some of the above listed marks in the European Community and Japan.

## Risk Factors

*You should carefully consider the risks and uncertainties described below, together with all other information included in this quarterly report and in our other public filings, before making any investment decision regarding our stock. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospectus would likely be materially and adversely affected. In that event, the market price of our stock could decline and you could lose all or part of your investment.*

### Risks Related to Our Business and Industry

*If our imaging systems and DIS services are not accepted by physicians or hospitals, we may be unable to develop a sustainable, profitable business.*

We expect that substantially all of our revenue in the foreseeable future will be derived from sales of our products in the nuclear imaging market and our leasing services offered through our wholly owned subsidiaries, Digirad Imaging Solutions, Inc. and Digirad Imaging Systems, Inc., which we refer to collectively as DIS. Our solid-state gamma cameras and DIS services represent a new approach in the nuclear imaging market. We began full commercial release of our imaging systems in March 2000 and established DIS in September 2000. Because of the recent commercial introduction of our nuclear imaging systems, we have limited product and brand recognition and our imaging systems have been used by a limited number of physicians and hospitals. Physicians and hospitals may generally be slow to adopt our products and leasing services for a number of reasons, including:

perceived liability risks generally associated with the use of new technologies for nuclear imaging;

availability of reimbursement from health care payors for procedures using our system;

lack of experience with our products and services;

costs associated with the purchase or lease of our products and services;

the presence of competing products sold by companies with longer operating histories, more recognizable names and more established distribution networks;

the introduction or existence of competing products and services or technologies that may be more effective, easier to use or that produce better images; and

physician and hospital perceptions of our imaging systems as compared to those of competitors.

Our success in the nuclear imaging market depends on whether physicians and hospitals view our imaging systems and DIS services as effective and economically beneficial. We believe that physicians and hospitals will not adopt our imaging systems or lease our DIS services unless they determine, based on experience and other factors, that our imaging systems and DIS services are an attractive alternative to vacuum tube imaging systems. We also believe that recommendations and support of our products and services by influential physicians and other health care providers are essential for market acceptance and adoption. We cannot assure you that physicians or hospitals will adopt or accept our imaging systems or DIS services. If physicians and hospitals do not adopt our imaging systems or DIS services, our operating results and business will be harmed.

*We sell our imaging systems and provide our services in a highly competitive industry, and we often compete against large, well-established competitors that have significantly greater financial resources than we have.*

The medical device industry, including the market for imaging systems and services, is highly competitive, subject to rapid change and significantly affected by new product introductions and market activities of other industry participants. Our primary competitors with respect to imaging systems include several large medical device manufacturers, including Philips Medical Systems, General Electric Healthcare, Siemens Medical Systems and Toshiba Medical Systems. All of these competitors offer a full line of imaging cameras for each diagnostic imaging technology, including x-ray, magnetic resonance imaging, computerized tomography, ultrasound and nuclear medicine. The existing imaging systems sold by our competitors have been in use for a longer time than our products and are more widely recognized and used by physicians

and hospitals for nuclear imaging. Many of our competitors and potential competitors enjoy significant competitive advantages over us, including:

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significantly greater name recognition and financial, technical and marketing resources;

established relationships with healthcare professionals, customers and third-party payors;

established distribution networks;

additional lines of products and the ability to offer rebates or bundle products to offer discounts or incentives; and

greater resources for product development, sales and marketing.

The competitive nature of the nuclear imaging industry has had an impact on the price of our gamma cameras. While we anticipate demand for our gamma cameras to continue to increase, we believe these pricing pressures will continue to impact our gamma camera product revenue and gross profit.

In providing comprehensive mobile nuclear imaging solutions, we generally compete against small businesses employing traditional vacuum tube cameras that must be transported in large vehicles and cannot be moved in and out of physician offices.

We are aware of certain major medical device companies that are attempting to develop solid-state cameras and we believe these efforts will continue. In addition, we are aware of a privately-held company, Gamma Medica, which is currently marketing a solid-state gamma camera for breast imaging. We do not believe that this camera can be used in a cardiac application. However, we cannot assure you that Gamma Medica will not attempt to modify its existing camera for use in the cardiac segment in the future, or develop another gamma camera for cardiac applications. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing competing products and services. Current or future competitors may develop technologies and products that demonstrate better image quality, ease of use or mobility than our imaging systems. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate reimbursement and are less expensive than alternatives available for the same purpose. If we are unable to compete effectively against our existing and future competitors our sales will decline and our business will be harmed.

***Changes in domestic and international legislation, regulation, or coverage and reimbursement policies of third-party payors may adversely impact our ability to market and sell our products and services.***

Physicians and hospitals purchasing and using our products rely on adequate third-party payor coverage and reimbursement to maintain their operations. Changes in domestic and international legislation, regulation or coverage and reimbursement policies of third-party payors may adversely affect the demand for our existing and future products and services and may limit our ability to market and sell our products and services on a profitable basis. For example, on December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003, or the Medicare Modernization Act, which contains a wide variety of changes that impact Medicare reimbursement to physicians and hospitals. We cannot predict what additional changes will be made to such legislation, regulation, or coverage and reimbursement policies, but we believe that future coverage and reimbursement may be subject to increased restrictions both in the United States and in international markets. Additionally, we cannot be certain that under prospective payment systems, or established fee schedule payment formulas, under which healthcare providers may be reimbursed a fixed amount based on the patient's condition or the type of procedure performed, the costs of our products and services will be justified and incorporated into the overall payment for the procedure. Third-party payors continue to act to contain or reduce healthcare costs through various means, including the movement to managed care systems where healthcare providers contract to provide comprehensive healthcare for a fixed fee per patient. These continued efforts to reduce healthcare costs may result in third-party payors refusing to reimburse patients or healthcare providers for our imaging services or allowing only specific providers to provide imaging services. As a result, sales of our gamma cameras would suffer and we may receive pressure from our customers to terminate or otherwise modify the lease arrangements for our DIS services. Under such circumstances, our business, financial condition and results of operations could be materially adversely affected.

***Because our imaging systems and DIS services are not widely diversified, a decrease in sales of our products and leasing services could seriously harm our business.***

Our current product and leasing service offerings consist primarily of our line of gamma cameras, including our Cardius-1, Cardius-2, 2020tc Imager and SPECTpak PLUS camera systems, each of which is used in the nuclear imaging market segment and all of which utilize the same solid-state technology. In addition, we offer a mobile imaging leasing service through DIS, which includes an imaging system, certified personnel, required licensure and other support for nuclear imaging procedures. As such, our line of products and services is not as diversified as those of some of our competitors. Consequently, if sales of our products or leasing services decline precipitously, our business would be seriously harmed, and it would likely be difficult for us to recover because we do not have the breadth of products or services that would enable us to sustain our business while seeking to develop new types of products or services or other markets for our existing products and services. In addition, because our technical know-how and intellectual property have limited applications, we may be unable to leverage our technical know-how and intellectual property to diversify our products and services or to develop other products or sources of revenue outside of the nuclear imaging market.





***Our imaging systems and DIS services may become obsolete, and we may not be able to timely develop new products, product enhancements or services that will be accepted by the market.***

Our nuclear imaging system and DIS services may become obsolete or unmarketable if other products or services utilizing new technologies are introduced by our competitors or new industry standards emerge. We cannot assure you that we will be able to successfully develop or market new products and services, or enhancements to our existing products, or that our future products and enhancements will be accepted by our current or potential customers or the third-party payors who financially support many of the procedures performed with our products. Any of these circumstances may cause us to lose customers, disrupt our business operations and harm our product sales and services. To be successful, we will need to enhance our products or services and to design, develop and market new products that successfully respond to competitive developments, all of which may be expensive and time consuming.

The success of any new product offering or enhancement to an existing product will depend on several factors, including our ability to:

properly identify and anticipate physician and patient needs;

develop new products or enhancements in a timely manner;

obtain the necessary regulatory approvals or clearances for new products or product enhancements in a timely manner;

provide adequate training to users of our products;

price our products competitively;

obtain appropriate coverage and receive adequate reimbursement notifications and respond to them in a commercially viable way;

comply with changing or new regulatory requirements; and

develop an effective marketing, sales and distribution network.

If we do not develop and obtain regulatory approvals or clearances for new products, services or product enhancements in time to meet market demand, or if there is insufficient demand for these products, services or enhancements, our business, financial condition and results of operations will likely suffer. In addition, even if our customers acquire new products, services or product enhancements we may offer, the revenues from any such products, services or enhancements may not be sufficient to offset the significant costs associated with offering such products, services or enhancements to customers. In addition, any announcements of new products, services or enhancements may cause customers to decline or cancel their purchasing decisions in anticipation of such products, services or enhancements.

***If we experience problems with the technologies used in our imaging systems or if delivery of our DIS services are delayed, public perception of us could be harmed and cause us to lose customers and revenue.***

Our gamma cameras have only recently been introduced into the marketplace. Most of our cameras currently in use are less than three years old. We have experienced some reliability issues with a prior version of our detector heads. In July 2003, we began selling most of our gamma cameras with a new version of our detector heads which has shown increased reliability, although other reliability issues remain. In addition, as the period of use of our cameras increases, other significant defects may occur. If significant defects do arise with our gamma cameras, our reputation among physicians and hospitals could be damaged.

Additionally, physicians rely on our DIS services to provide nuclear imaging procedures to their patients on the dates and at the times they have requested. Many factors could prevent us from delivering our DIS services on a timely basis, including weather and the availability of staffing, transportation and necessary supplies. If we are unable to provide physicians or hospitals our DIS services in a timely and effective manner, our reputation among physicians and hospitals could be damaged.

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The performance and reliability of our products and services are critical to our reputation and to our ability to achieve market acceptance of those products and services. Widespread or other failures of our cameras and other products to consistently meet the expectations of purchasers or customers that use our DIS services could adversely affect our reputation, our ability to provide our DIS services, our relations with current customers and our business operations. Such failures could also reduce the attractiveness of our products and services to potential customers. Equipment failures could result from any number of causes, including equipment aging, ordinary wear and tear due to regular transportation and relocation, failure to perform routine maintenance and latent hardware or software defects of which we are unaware. Such failures, whether actual or perceived, could adversely affect our business even if we correct the underlying problems.

***Our manufacturing operations are highly dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business.***

We rely on a limited number of third parties to manufacture and supply certain of the key components of our products. While many of the components used in our products are available from multiple sources, we obtain some components from single sources. For example, key components of the detector heads and the acquisition and control software utilized in our gamma cameras are manufactured or supplied by a single source. To be successful, our contract manufacturers and suppliers must provide us with the components of our systems in requisite quantities, in compliance with regulatory requirements, in accordance with agreed-upon specifications, at acceptable cost and on a timely basis. Segami Corporation, or Segami, has developed image acquisition and processing software for our camera under a non-exclusive license agreement. In the event that Segami attempts to terminate the license agreement, refuses to extend the term of the license or seeks to impose unreasonable pricing or terms, we would have to find an alternative software system to use in our gamma camera. Our reliance on these outside suppliers subjects us to a number of risks that could harm our business, including:

suppliers may make errors in manufacturing components that could adversely affect the efficacy or safety of our products or cause delays in shipment of our products;

we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;

we may have difficulty locating and qualifying alternative suppliers for our components;

once we identify alternative suppliers, we could experience significant delays in production due to the need to evaluate and test the products delivered by alternative suppliers and to obtain regulatory qualification for them;

we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;

we use some suppliers that are small, privately-held companies, and these suppliers could encounter financial or other difficulties that could cause them to modify or discontinue their operations at any time;

our suppliers manufacture products for a range of customers, and fluctuations in demand for the products those suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and

our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive procedures. These events could harm our business and operating results.

***We have limited marketing, sales and distribution capabilities, and our efforts in those areas are dependent in part on third parties.***

We began commercial production and shipped our first imaging products in 2000, and therefore have limited experience in marketing, selling and distributing our products and services. Additionally, while we have a direct sales team focused on domestic marketing, sales and distribution, we also use four independent distributors in the United States and two independent, international sales distributors to market, sell and distribute our products and services. As a result, we are dependent in part upon the marketing, sales and distribution efforts of our third-party distributors. To date, one of our domestic third-party distributors is permitted to market, sell and distribute competing imaging services and products. Additionally, one of our domestic third-party distributors, as well as one of our international distributors, is generally permitted to market, sell and distribute competing imaging products that are used or refurbished and meet specified age requirements. Our other international distributor is prohibited from promoting or distributing any other gamma camera product, but is not prohibited from offering competing services.

Our future revenue growth will depend in large part on our success in maintaining and expanding our marketing, sales and distribution channels, which will likely be an expensive and time-consuming process. We are highly dependent upon the efforts of our sales force and third-party distributors to increase our revenue. We face intense competition for qualified sales employees and may be unable to hire, train, manage and retain such personnel, which could adversely affect our ability to maintain and expand our marketing, sales and distribution network, which would negatively affect our ability to compete effectively as a distributor of nuclear imaging devices. Additionally, even if we are able to expand our sales force and enter into agreements with additional third-party distributors on commercially reasonable terms, they may not commit the necessary resources to effectively market, sell and distribute our products and services domestically and internationally. If we are unable to maintain and expand our direct and third-party marketing, sales and distribution networks, we may be unable to sell enough of our products and imaging services for our business to be profitable and our financial condition and results of operations will likely suffer accordingly.

***We are subject to the financial risks associated with providing services through our DIS business.***

There are numerous risks associated with any leasing arrangement, including the possibility that physicians may fail to make the required payments under the terms and provisions of their lease commitments. Our DIS business is also affected by the ability of physicians to pay us, which in turn may be affected by general economic and business conditions and the availability of reimbursement for the physicians. Such circumstances could adversely affect our business and financial condition.

***If we are unable to expand our DIS business, our business could be materially harmed.***

We plan to grow our DIS business by expanding into several new states, adding new hub locations in states in which we currently operate and increasing hub utilization by adding physician customers and routes. As we undertake this expansion, we will need to hire, train and retain qualified personnel. We cannot assure you that physicians or hospitals in these new markets will accept our imaging products or services. Our expansion into additional domestic markets is subject to inherent risk, including the burden of complying with applicable state regulations, including but not limited to regulations concerning the use, storage, handling and disposal of radioactive materials, the difficulties in obtaining the necessary radioactive licensures and difficulties in staffing and managing operations. Furthermore, physician self-referral laws currently in effect in the State of New York do not allow the conduct of our DIS business as it is currently structured or at all, and we may find the laws of other states in which we do not currently operate to require us to change the structure of our DIS business to operate in such states.

***A loss of key executives or failure to attract qualified managers, engineers and imaging technologists could limit our growth and adversely affect our business.***

Our success is dependent on the efforts of our key technical, sales and managerial personnel and our ability to retain them. The loss of any one or more of these individuals could place a significant strain on our remaining management team and we may have difficulty replacing any of these individuals. Furthermore, our future growth will depend in part upon our ability to identify, hire and retain additional key personnel, including nuclear imaging technologists, paramedics, nurses, radiation safety officers, engineers, management, sales personnel and other highly skilled personnel. Hiring qualified management and technical personnel will be difficult due to the limited number of qualified candidates. Competition for these types of employees, particularly nuclear imaging technologists and engineers, is intense in the medical imaging field. Given the competition for such qualified personnel, we cannot assure you that we will be able to continue to attract, hire and retain the personnel necessary to maintain and develop our business. Failure to attract, hire and retain key personnel could have an adverse effect on our business, financial condition and results of operations. We do not have any employment agreements with, or key person insurance on, any of our employees.

***If we choose to acquire new or complementary businesses, products or technologies instead of developing them ourselves, we may be unable to complete those acquisitions or to successfully integrate them in a cost-effective and non-disruptive manner.***

Our success depends on our ability to continually enhance and broaden our product and service offerings in response to changing customer demands, competitive pressures and technologies. While we have no current plans or commitments regarding any acquisitions of new or complementary businesses, products or technologies, we may in the future choose to pursue such acquisitions instead of developing those businesses, products or technologies ourselves. We cannot assure you, however, that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology into our company in a cost-effective and non-disruptive manner. Furthermore, there is no certainty that we would be able to attract, hire or retain key employees associated with any acquired businesses, products or technologies.

Integrating any acquired businesses, products or technologies could be expensive and time consuming, disrupt our ongoing business and divert the attention and resources of our management. If we are unable to integrate any acquired businesses, products or technologies effectively, our business will likely suffer. Additionally, any amortization of assets or charges resulting from the costs of acquisitions could harm our business and operating results.



*We will face additional risks as we expand into international markets.*

We have sales distributors for our imaging systems in Canada and Russia and are beginning to build an international sales organization. As we expand internationally, we will need to hire, train and retain qualified personnel in countries where language, cultural or regulatory impediments may exist. We cannot assure you that distributors, physicians or other involved parties in foreign markets will accept our nuclear imaging products, services and business practices. Our international operations will be subject to inherent risks, including:

costs of localizing product and service offerings for foreign markets;

difficulties in staffing and managing foreign operations;

reduced protection for intellectual property rights in some countries;

difficulties and delays in enforcing agreements and in collecting receivables through the legal systems of foreign countries;

fluctuating currency exchange rates;

the possibility that foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;

changes in political, regulatory, or economic conditions in a country or region;

our ability to obtain U.S. export licenses and other required export or import licenses or approvals;

burdens of complying with a wide variety of foreign laws, regulations specific to the delivery of and payment for healthcare services, regulations and licensing requirements relating to the use, storage, handling and disposal of radioactive materials, labor practices; and

conforming our business model to operate under government-run healthcare systems.

***Our manufacturing operations and executive offices are located at a single facility that may be at risk from fire, earthquakes or other natural or man-made disasters or crises.***

Our manufacturing operations and executive offices are located at a single facility in Poway, California, near known fire areas and earthquake fault zones. This facility is located a short distance from the recent wildfires that destroyed many homes and businesses in San Diego County, California. We have taken precautions to safeguard our facilities, including insurance and health and safety protocols. However, any future natural disaster, such as a fire or an earthquake, could cause substantial delays in our operations, damage to or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. A disaster could significantly harm our business and results of operations. The insurance we maintain against fires and other natural disasters may not be adequate to cover our losses in any particular case.

Additionally, electrical power is vital to our operations and we rely on a continuous power supply to conduct our business. California has experienced significant electrical power shortages and price volatility in recent years, and such shortages and price volatility may occur in the future. In the event of an acute power shortage, the California system operator has on some occasions implemented, and may in the future implement, rolling blackouts throughout California. If our energy costs substantially increase or blackouts interrupt our power supply frequently or for more than a few days, we may have to reduce or temporarily discontinue our normal operations. In addition, the cost of our research and development efforts may increase because of the disruption to our operations. Any such reduction or disruption of our operations at our facilities could harm our business.

*We are exposed to risks relating to product liability, product recalls, property damage and personal injury for which insurance coverage is expensive, limited and potentially inadequate, and our business may be impacted by increased insurance costs.*

Our operations entail a number of risks, including risks relating to product liability claims, product recalls, property damage and personal injury. We currently maintain insurance that we believe is adequate with respect to the nature of the risks insured against, including product liability insurance, professional liability insurance, automobile insurance, property insurance, workers compensation insurance and general liability insurance. In many cases such insurance is expensive and difficult to obtain, and no assurance can be given that we will be able to maintain our current insurance or that we will be able to obtain or maintain comparable or additional insurance in the future on reasonable terms, if at all. Additionally, we may be negatively affected by increased costs of insurance, including workers compensation insurance. For example, in October 2003, the Governor of California signed a bill which will take effect in January 2006, which will require California businesses with 50 or more employees either to pay at least 80% of the premiums for a basic individual health insurance package for each of its employees and their families, or to pay a fee into a state pool for the purchase of health insurance for uninsured, low income workers.

#### **Risks Related to Our Financial Results and Need for Financing**

*We have incurred significant and recurring operating losses since our inception in 1985 and we expect to incur increased operating expenses in the near term.*

We have incurred significant net losses since our inception in November 1985 and as of June 30, 2004, we had an accumulated deficit of \$80.5 million. We expect to incur increased operating expenses in the near term as we, among other things:

expand our manufacturing operations and DIS business;

increase marketing, sales and distribution of our current products; and

conduct research and development to develop next-generation products and to enhance our existing products.

As a result of these activities, we may not be able to maintain profitability. If our revenue grows more slowly than anticipated, or if our operating expenses exceed our expectations, our ability to achieve our development and expansion goals would be adversely affected.

*Our quarterly financial results are difficult to predict and are likely to fluctuate significantly from period to period because our business prospects are uncertain and due to the seasonality of our DIS leasing services business.*

Our revenue and results of operations at any given time will be primarily based on the following factors, many of which we cannot control:

physician, healthcare provider and patient acceptance of our products and services;

demand and pricing of our products and services;

success and timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;

our ability to establish and maintain a productive manufacturing, marketing, sales and distribution force;

the ability of our suppliers to timely provide us with an adequate supply of necessary components;

timing and magnitude of our expenditures;

our ability to reduce our expenses, including our debt service obligations, quickly enough to respond to any declines in revenue;

regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;

the effect of competing technological and market developments;

our addition or termination of research programs or funding support;

levels of third-party reimbursement for our products and services;

interruption in the manufacturing or distribution of our products and services; and

changes in our ability to obtain FDA approval or clearance for our products.

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Furthermore, we have experienced seasonality in the leasing services offered by DIS. While our physicians are obligated to pay us for all lease days to which they have committed, our contracts permit some flexibility in scheduling when services are to be performed. This accounts for some of the seasonality of our DIS revenues. For example, our daily services have typically declined from our second fiscal quarter to our third fiscal quarter due to summer holidays and vacation schedules. We have also experienced declining daily services in December due to holidays and in our first quarter due to weather conditions in certain parts of the United States. We cannot predict with certainty the degree to which seasonal circumstances such as the summer slowdown, winter holiday variations and weather conditions may make our revenue unpredictable or lead to fluctuations in our quarterly operating results in the future.

In addition, due to the way that customers in our target markets acquire our products, a large percentage of our orders of gamma cameras is booked during the last month of each quarterly accounting period. As such, a delivery delay of only a few days may significantly impact our quarter-to-quarter comparisons.

For these reasons, we believe that quarterly sales and operating results may vary significantly in the future and that period-to-period comparisons of our results of operations are not necessarily meaningful and should not be relied upon as indicators of future performance. We cannot assure you that our sales will increase or be sustained in future periods. Accordingly, we may experience significant, unanticipated quarterly losses. Because of these and other factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline significantly.

***Our reliance on a limited number of customers may cause our sales to be volatile.***

We currently have a small number of customers, whom we typically bill after the delivery of our products and imaging services. If orders for our gamma cameras were to be cancelled, or our leasing service customers stopped using us or do not renew their lease agreements with us, our business would be adversely affected. Furthermore, in view of our small customer base, our failure to gain additional customers, the loss of any current customers or a significant reduction in the level of leasing services provided to any one customer could disrupt our business, harm our reputation and adversely affect our sales.

***The sales cycle for our gamma cameras is typically lengthy, which may result in significant fluctuations in our revenue.***

Our sales efforts for our gamma cameras are dependent on the capital expenditures budgets of the physicians and hospitals to which we market. Often physicians and hospitals require a significant amount of lead time to plan for a major acquisition such as the purchase of our imaging systems. We may spend substantial time, effort and expense long before we actually consummate an order of our cameras and with no assurance that we will ultimately be successful in achieving any such orders. As a result, we may experience significant fluctuations in our revenues. Furthermore, evaluating and predicting our future sales and operating performance is difficult and may not be as accurate as it could be if we had shorter sales cycles.

***Our future capital needs are uncertain and we may need to raise additional funds in the future, and such funds may not be available on acceptable terms, if at all.***

Although we believe that our current cash and cash equivalents will be sufficient to meet our projected operating requirements for the foreseeable future, our capital requirements will depend on many factors, including:

- the revenue generated by sales of our products and services;
- the costs associated with expanding our manufacturing, marketing, sales and distribution efforts;
- the rate of progress and cost of our research and development activities;
- the costs of obtaining and maintaining FDA and other regulatory clearance of our products and products in development;
- the costs of obtaining and maintaining radioactive materials licenses and radiation safety procedures;
- the effects of competing technological and market developments;
- the number and timing of acquisitions and other strategic transactions; and
- the costs associated with our expansion, if any.



As a result of these factors, we may need to raise additional funds, and we cannot be certain that such funds will be available to us on acceptable terms, if at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our future products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to expand our operations, develop new products, take advantage of future opportunities or respond to competitive pressures or unanticipated customer requirements.

### **Risks Related to Government Regulation**

*We must be licensed to handle and use hazardous materials and may be liable for contamination or other harm caused by hazardous materials that we use.*

We use hazardous and radioactive materials in our research and development and manufacturing processes, as well as in the provision of our imaging services. We are subject to federal, state and local regulations governing use, storage, handling and disposal of these materials and waste products. We are currently licensed to handle such materials in all states in which we operate, but there can be no assurances that we will be able to retain those licenses in the future. In addition, we must become licensed in all states in which we plan to expand. Obtaining those additional licenses is an expensive and time consuming process, and in some cases we may not be able to obtain those licenses at all.

Although we believe that our procedures for use, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources and any applicable insurance.

We have also incurred and may continue to incur expenses related to compliance with environmental laws. Such future expenses or liability could have a significant negative impact on our business, financial condition and results of operations. Further, we cannot assure you that the cost of complying with these laws and regulations will not materially increase in the future.

*Compliance with extensive product regulations could be expensive and time consuming, and any failure to comply with those regulations could harm our ability to sell and market our products and imaging services.*

U.S. and foreign regulatory agencies, including the FDA, govern the testing, marketing and registration of new medical devices or modifications to medical devices, in addition to regulating manufacturing practices, reporting, labeling and recordkeeping procedures. The regulatory process makes it longer, harder and more costly to bring our products to market, and we cannot assure you that any of our future products will be approved. All of our planned services, products and manufacturing activities, as well as the manufacturing activities of third-party medical device manufacturers who supply components to us, are subject to these regulations. Generally, we and our third-party manufacturers are or will be required to:

undergo rigorous inspections by domestic and international agencies;

obtain the prior approval of those agencies before we can market and sell our medical device products; and

satisfy content and format requirements for all of our sales and promotional materials.

Compliance with the regulations of those agencies may delay or prevent us from introducing new or improved products, which could in turn affect our ability to achieve or maintain profitability. We may be subject to sanctions, including monetary fines and criminal penalties, the temporary or permanent suspension of operations, product recalls and marketing restrictions, if we fail to comply with the laws and regulations applicable to our business. Our third-party component manufacturers may also be subject to the same sanctions and, as a result, may be unable to supply components for our products. Any failure to retain governmental approvals that we currently hold or obtain additional similar approvals could prevent us from successfully marketing our products and technology and could harm our operating results. Furthermore, changes in the applicable governmental regulations could prevent further commercialization of our products and technologies and could harm our business.

Even if regulatory approval or clearance of a product is granted, regulatory agencies could impose limitations on uses for which the product may be labeled and promoted. Further, for a marketed product, its manufacturer and manufacturing facilities are subject to periodic review and inspection. Later discovery of problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market or other enforcement actions.

***Our products are subject to reporting requirements and recalls even after receiving FDA clearance or approval, which could harm our reputation, business and financial results.***

We are subject to medical device reporting regulations that require us to report to the FDA or similar governmental bodies in other countries if our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to recur. In addition, the FDA and similar governmental bodies in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall would divert management attention and financial resources and harm our reputation with customers. A recall involving our product could harm the reputation of the product and our company and would be particularly harmful to our business and financial results.

***If we fail to obtain, or are significantly delayed in obtaining, FDA clearances or approvals for future products or product enhancements, or if we fail to comply with FDA's Quality System Regulation, our ability to commercially market and distribute our products will suffer.***

Our products are subject to rigorous regulation by the FDA, and numerous other federal, state and foreign governmental authorities. In the U.S., the FDA regulates virtually all aspects of a medical device's testing, manufacture, safety, labeling, storage, recordkeeping, reporting, promotion and distribution. Our failure to comply with those regulations could lead to the imposition of administrative or judicial sanctions, including injunctions, suspensions or the loss of regulatory approvals, product recalls, termination of distribution, or product seizures. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities are possible. The process of obtaining regulatory approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such approvals will be granted on a timely basis, if at all. In particular unless exempt, the FDA permits commercial distribution of a new medical device only after the device has received 510(k) clearance or is the subject of an approved Premarket Approval Application, or PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA approval process is more costly, lengthy and uncertain than the 510(k) clearance process, and must be supported by extensive data, including data from preclinical studies and human clinical trials. Because we cannot assure you that any new products we develop, or any product enhancements, will be subject to the shorter 510(k) clearance process, significant delays in the introduction of any new products or product enhancements may occur. While we have not been required to obtain PMA approval for any of our products, there is no assurance that the FDA will not require a new product or product enhancement go through the lengthy and expensive PMA approval process. Further, pursuant to FDA regulations, we can only market our products for approved uses. If our products are used for purposes other than those approved by the FDA, the FDA could object to such off-label uses.

Our manufacturing processes and those of our third-party manufacturers are required to comply with the FDA's Quality System Regulation, which covers the design, testing, production processes, controls, quality assurance, labeling, packaging, storage and shipping of our devices. In addition, we must engage in extensive recordkeeping and reporting and must make available our manufacturing facility and records for periodic unscheduled inspections by federal, state and foreign agencies, including the FDA. Our or our third-party manufacturers' failure to pass a Quality System Regulation inspection or to comply with these and other applicable regulatory requirements could result in disruption of our operations and manufacturing delays, and a failure to take adequate corrective action could result in, among other things, withdrawal of our medical device clearances, seizure or recall of our devices, or other civil or criminal enforcement actions.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we now or in the future market and sell our products in foreign countries, we may be subject to rigorous regulation by those foreign governmental authorities. In such circumstances, we would rely significantly on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries.

***Modifications to our products may require new 510(k) clearances or premarket approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.***

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA requires us to seek 510(k) clearance or PMA for modification of a previously cleared product for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in delays, fines, costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.

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*We will spend considerable time and money complying with federal, state and foreign regulations and, if we are unable to fully comply with such regulations, we could face substantial penalties.*

We are directly or indirectly through our clients, subject to extensive regulation by both the federal government and the states and foreign countries in which we conduct our business. The laws that directly or indirectly affect our ability to operate our business include, but are not limited to, the following:

the federal Medicare and Medicaid Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs;

other Medicare laws and regulations that prescribe the requirements for coverage and payment for services performed by us and our DIS customers, including the amount of such payment;

the federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program, including private payors and, further, requires us to comply with standards regarding the privacy and security of individually identifiable health information and conduct certain electronic transactions using standardized code sets. In addition, regulations have been issued under HIPAA that will require us to comply with additional security regulations by April 2005 and to adopt unique health identifiers for use in filing and processing healthcare claims and other transactions by May 2007;

the federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

the federal physician self-referral prohibition, commonly known as the Stark Law, which, in the absence of a statutory or regulatory exception, prohibits the referral of Medicare patients by a physician to an entity for the provision of certain designated healthcare services, if the physician or a member of the physician's immediate family has a direct or indirect financial relationship, including an ownership interest in, or a compensation arrangement with, the entity and also prohibits that entity from submitting a bill to a federal payor for services rendered pursuant to a prohibited referral;

the federal Food, Drug and Cosmetic Act, which regulates the manufacture, labeling, marketing, distribution and sale of prescription drugs and medical devices;

state and foreign law equivalents of the foregoing;

federal and state radioactive materials laws, which govern the procurement, use, transfer and storage of radioactive materials;

state food and drug laws, pharmacy acts and state pharmacy board regulations, which govern the sale, distribution, use, administration and prescribing of prescription drugs;

state laws that prohibit the practice of medicine by non-physicians and fee-splitting arrangements between physicians and non-physicians, as well as state law equivalents to the federal Medicare and Medicaid Anti-Kickback Law and the Stark Law, which may not be limited to government reimbursed items or services; and

federal laws and regulations that permit physicians to bill and receive payment for certain diagnostic tests under the Medicare Physician Fee Schedule only if certain conditions are satisfied, including the requirement that the physician personally perform, or adequately supervise the performance of, the test using equipment they own or lease, and that prohibit physicians from marking up the cost of tests they purchase, rather than perform or supervise, for Medicare patients.

We implemented a compliance program in 2002 to help assure that we remain in compliance with these laws. Like most companies with active and effective compliance programs, we occasionally discover compliance concerns. For example, we have discovered certain isolated arrangements that we entered into in good faith but that, upon review by our compliance personnel, raised some compliance concerns under these laws. In accordance with our compliance program, we took immediate remedial steps. We cannot assure you that these remedial steps will insulate us from liability associated with these isolated arrangements.

If our past or present operations are found to be in violation of any of the laws described above or the other governmental regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our customers are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. In addition, if we are required to obtain permits or licensure under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations, and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

***Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably.***

In both the United States and certain other foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products and services profitably. In the United States, federal and state lawmakers regularly propose and, at times, enact new legislation establishing significant changes in the healthcare system. Recently, President Bush signed into law the Medicare Modernization Act, which contains a wide variety of reforms that impact Medicare reimbursements to hospitals and physicians including changes to Medicare payment methodologies for radiopharmaceuticals and other drugs dispensed by hospital outpatient departments and for drugs dispensed by physician offices and independent diagnostic testing facilities. These changes reduced payment amounts for some of the drugs used in conjunction with our imaging procedures, although the physician fee schedule payment rates applicable to nuclear cardiology increased slightly. Downward changes to Medicare reimbursement rates may adversely impact reimbursement to customers or potential customers that use or could use our cameras and services. We cannot predict the full impact that this new legislation will have nor whether new federal legislation will be enacted in the future. The potential for adoption of healthcare reform proposals on a state-by-state basis could require us to develop state-specific marketing and sales approaches. In addition, we may experience pricing pressures in connection with the sale of our products and services due to additional legislative proposals or healthcare reform initiatives. Our results of operations and our business could therefore be adversely affected by future healthcare reforms.

***The impact of regulatory changes could have a negative impact on camera sales to and leases with hospitals desiring to use our cameras and services in their outpatient facilities.***

In order for hospitals to receive certain payments for their outpatient facilities as hospital outpatient services, including services that utilize our products, these services must be furnished in a provider-based organization or facility or be covered services furnished under arrangement with the hospital. Failure to meet these requirements may result in reduced payments to the hospitals for their services. The Medicare program has published and revised rules establishing criteria for classifying a facility as provider-based or a service as furnished under arrangement. These rules require an analysis of the facts and circumstances surrounding the delivery by a hospital of a particular service, and hospitals that use our products or DIS services in their outpatient facilities will need to determine if they meet the applicable provider-based or under arrangement requirements. Hospitals that cannot obtain sufficient payments for these services may not purchase a camera from us or enter into arrangements with us for provision of services.

***The application of state certificate of need regulations could harm our business and financial results.***

Some states currently require, or may require in the future, a certificate of need or similar regulatory approval prior to the acquisition of high-cost capital items, including diagnostic imaging systems, or provision of diagnostic imaging services by us or our clients. In many cases, a limited number of these certificates are available in a given state. If we or our clients are unable to obtain the applicable certificate or approval or additional certificates or approvals necessary to expand our operations, these regulations may limit or preclude our operations in the relevant jurisdictions.

*If we fail to comply with various licensure, or certification standards, we may be subject to loss of licensure or certification, which would adversely affect our operations.*

All of the states in which we operate require that the imaging technicians that operate our cameras be licensed or certified. Obtaining such licenses may take significant time as we expand into additional states. Any lapse in the licensure or certification of our technicians could increase our costs and adversely affect our operations and financial results. Further, we are currently enrolled by Medicare contractors, or carriers, as an independent diagnostic testing facility in nine states where we are or were operating under our mixed bill model, and enrollment is essential for us to receive payment for healthcare services directly from Medicare. We are phasing out our mixed bill operations and, as of August 1, 2004, derive less than one percent of our DIS revenues from such operations.

In the healthcare industry, various types of organizations are accredited to facilitate meeting certain Medicare certification requirements, expedite third-party payment and fulfill state licensure requirements. Some managed care providers prefer to contract with accredited organizations. Thus far, we have not found it necessary to seek or obtain accreditation from any established accreditation agency. If it becomes necessary for us to do so in the future in order to satisfy the requirements of third-party payors or regulatory agencies, there can be no assurances that we will be able to obtain or continuously maintain this accreditation.

*Audits or denials of our claims, or claims submitted by our DIS customers, by government agencies or contractors could reduce our revenues or profits and expose us to claims.*

Under our mixed bill model, we submit claims directly to and receive payments directly from the Medicare program. Therefore, we are subject to extensive government regulation, including requirements for maintaining certain documentation to support our claims. Government agencies and Medicare contractors also may conduct inspections or surveys of our facilities, payment reviews and other audits of our claims and operations. For example, as part of a national audit conducted pursuant to the 2003 work plan, the Office of the Inspector General of the U.S. Department of Health and Human Services, or the OIG, conducted a review of one of our independent diagnostic testing facilities in early 2003 to review the appropriateness of Medicare payments received. This audit was concluded without any action being taken by the OIG. While we believe this audit will have no impact on us, we cannot assure you that the OIG may not take some follow-up action. We may be subject to investigations, payment reviews and audits and cannot assure you that such scrutiny will not result in material delays in payment, as well as material recoupments or denials, which could reduce our revenue or profits. Our DIS customers also submit claims to Medicare and other third-party payors, are subject to the same types of regulation and scrutiny, and may experience the same types of problems. This could adversely affect our ability to market our leases and services and to maintain existing contracts.

#### **Risks Related to Our Intellectual Property and Potential Litigation**

*Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain.*

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our pending U.S. and foreign patent applications, which include claims to material aspects of our products and procedures that are not currently protected by issued patents, may not issue as patents in a form that will be advantageous to us. Any patents we have obtained or do obtain may be challenged by re-examination or otherwise invalidated or eventually found unenforceable. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may attempt to challenge or invalidate our patents, or may be able to design alternative techniques or devices that avoid infringement of our patents, or develop products with functionalities that are comparable to ours. Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, advisors and corporate partners, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

In the event a competitor infringes upon our patent or other intellectual property rights, litigation to enforce our intellectual property rights or to defend our patents against challenge, even if successful, could be expensive and time consuming and could require significant time and attention from our management. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents against challenges from others.

We have entered into a royalty-bearing license for one U.S. patent with a third-party for use in nuclear imaging, which license is co-exclusive with the U.S. government. In July 2004, we settled our dispute concerning this license and retain the license co-exclusively at more favorable licensing terms.



***The medical device industry is characterized by patent litigation and we could become subject to litigation that could be costly, result in the diversion of our management's time and efforts, and require us to pay damages.***

The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that our products, their components or the methods we employ in the use of our products are covered by U.S. or foreign patents held by them. In addition, they may claim that their patents have priority over ours because their patents were filed or invented earlier. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware, which may later result in issued patents that our products may infringe. There could also be existing patents that one or more components of our products may be infringing of which we are unaware. As the number of participants in our industry increases, the possibility of patent infringement claims against us also increases.

Any litigation or claims against us may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of our management from our core business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to be inadvertently infringing, we could be required to pay substantial damages and/or royalties and could be prevented from selling our products unless we could obtain a license or were able to redesign our system to avoid infringement. Any such license may not be available on reasonable terms, if at all. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may be unable to commercialize one or more of our products.

***We rely significantly on a license agreement with Segami Corporation for the imaging acquisition and processing software for our digital gamma camera, and the loss of the license could result in delivery delays, loss of customers and loss of revenue.***

Segami Corporation, or Segami, has developed image acquisition and processing software for our camera under a non-exclusive license agreement. In the event that Segami attempts to terminate the license agreement, refuses to extend the term of the license or seeks to impose unreasonable pricing or terms, we would have to find an alternative software system to use in our gamma camera. To our knowledge, there are a limited number of companies that would be able to develop and implement a software system similar to what we use in our gamma camera. As a result, in the event that we were unable to continue to use the software under the license from Segami, we could have delays in the production of our gamma camera as we attempted to find a substitute software provider. Furthermore, we cannot guarantee that alternative software providers would be able to meet our requirements or that their software would be available to us at favorable prices, if at all. To the extent we were unable to find an alternative source for the software, we may have to develop our own software system. We cannot guarantee that we could internally develop such a software system or that such efforts would not divert resources away from the development of other features of our camera. As a result, locating an alternative software system or developing our own software system could interrupt the manufacture and delivery of our products for an extended period of time and may cause the loss of customers and revenue.

***We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of their former employers.***

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hinder or preclude our ability to commercialize our products, which could severely harm our business.

***If we become subject to product liability or warranty claims, we may experience reduced demand for our products or be required to pay damages that exceed our insurance coverage.***

The sale and support of our products entails the risk of product liability or warranty claims, such as those based on claims that the failure of one of our products resulted in a misdiagnosis, among other issues. The medical device industry has been subject to significant products liability litigation. We may incur significant liability in the event of any such litigation, regardless of the merit of the action. Although we maintain product liability insurance, we cannot be sure that this coverage is adequate or that it will continue to be available on acceptable terms, if at all. We also may face warranty exposure, which could adversely affect our operating results. Any unforeseen warranty exposure or insufficient insurance could harm our business, financial condition and results of operations. Finally, even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and could result in the diversion of management's attention from managing our business.

*We may be subject to lawsuits and actions brought by our employees.*

We may from time to time be subject to employment claims or disputes. In June 2004, we settled allegations by one former and three present employees claiming that they were due overtime pay because of an alleged misclassification of their positions as non-exempt rather than exempt employees. However, we cannot assure you that we may not be subject to other lawsuits and actions brought by our employees or that we would be successful defending against such actions. Any employment claims could significantly divert our management's time and attention and could materially affect our business.

**Risks Related to the Securities Markets and Ownership of Our Common Stock**

*There has been no prior public market for our common stock and an active trading market may not develop*

Prior to our initial public offering, there had been no public market for our stock. An active trading market for our common stock may not develop in the future or, if it is developed, may not be sustained. An inactive market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. Furthermore, an inactive market may impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, products and technologies by using our shares as consideration.

*Future sales of our common stock may cause our stock price to decline.*

A small number of our current stockholders hold a substantial number of shares of our common stock that they will be able to sell in the public market in the near future. Sales by our current stockholders of a substantial number of shares, or the expectation that such sale may occur, could significantly reduce the market price of our common stock. Moreover, as of June 30, 2004, the holders of approximately 12,546,496 shares of common stock, including shares issued upon the exercise of certain of our warrants, will have rights, subject to some conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders. Although the holders of most of our outstanding capital stock have agreed with the underwriters of our initial public offering to be bound by a 180-day lock-up agreement that prohibits these holders from selling or transferring their stock, other than in specific circumstances, Merrill Lynch, Pierce, Fenner & Smith Incorporated and J.P. Morgan Securities Inc., at their discretion, can waive the restrictions of the lock-up agreement at an earlier time without prior notice or announcement and allow our stockholders to sell their shares of our common stock in the public market. If the restrictions of the lock-up agreement are waived, shares of our common stock will be available for sale into the market, subject only to applicable securities rules and regulations, which may cause our stock price to decline.

We have also registered all common stock that we may issue under our 2004 Stock Incentive Plan and 2004 Non-Employee Director Stock Option Program. Accordingly, they can be freely sold in the public market upon issuance, subject to restrictions under the securities laws and the lock-up agreements described above. If any of these stockholders cause a large number of securities to be sold in the public market, the sales could reduce the trading price of our common stock. These sales also could impede our ability to raise future capital.

*Our stock price may be volatile.*

The market price for our common stock is likely to be volatile. In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

- volume and timing of orders for our products and services;
- the introduction of new products, product enhancements, services or technologies by us or our competitors;
- quarterly variations in our or our competitors' results of operations;
- conditions or trends in the medical device industry and the imaging service industry;
- disputes or other developments with respect to intellectual property rights;
- our ability to develop, obtain regulatory clearance for, and market, new and enhanced products on a timely basis;
- product liability claims or other litigation;
- additions or departures of key personnel;



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sales of large blocks of our common stock, including sales by our executive officers and directors;

changes in governmental regulations or in the status of our regulatory approvals or applications;

changes in the availability of third-party reimbursement in the United States or other countries;

changes in earnings estimates or recommendations by securities analysts; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

***Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change in control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.***

Our restated certificate of incorporation and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions include:

prohibiting our stockholders from calling a special meeting of stockholders unless they hold not less than 20% of the total number of votes to be cast at such a meeting;

permitting the issuance of additional shares of our common stock or preferred stock without stockholder approval;

prohibiting our stockholders from making certain changes to our restated certificate of incorporation or restated bylaws except with 66<sup>2</sup>/<sub>3</sub>% stockholder approval; and

requiring advance notice for raising matters of business or making nominations at stockholders' meetings.

We are also subject to provisions of the Delaware corporation law that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for five years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

***We may become involved in securities class action litigation that could divert management's attention and harm our business.***

The stock market in general, and the Nasdaq National Market and the market for medical device companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the companies in those markets. In addition to our performance, these broad market and industry factors may materially harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could materially harm our financial condition and results of operations.

***If our officers, directors and principal stockholders choose to act together, they may be able to control our management and operations, acting in their best interests and not in the best interests of other stockholders.***

Our officers, directors and holders of 5% or more of our outstanding common stock beneficially own the majority of our outstanding common stock. As a result, these stockholders, acting together, will be able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders. As a result of their actions or inactions our stock price may decline.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio and on the increase or decrease in the amount of interest expense we must pay on our various outstanding debt instruments. Our risk associated with fluctuating interest rates is limited, however, to certain of our long-term debt and capital lease obligations, all of which have interest rates that are closely tied to market rates, and our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments. Changes in interest rates over time will increase or decrease our interest income and interest expense.

**ITEM 4. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports pursuant to the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Securities Exchange of 1934, as amended, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 2. CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

(c) During the quarter ended June 30, 2004, we issued and sold the following unregistered securities:

On April 22, 2004, we granted options to purchase 62,000 shares of common stock to employees, directors and consultants under our 1998 Stock Option/Stock Issuance Plan at an exercise price of \$6.51 per share. During such period of time, 39,150 shares of common stock were purchased pursuant to the exercise of stock options for cash consideration with an aggregate exercise price of \$19,184. The offers, sales and issuances of the options and common stock were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance on Rule 701 because the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such options and common stock were our employees, directors or bona fide consultants and received the securities under our 1998 Stock Option/Stock Issuance Plan. Appropriate legends were affixed to the share certificates issued in such transactions, and each of these recipients had adequate access, through employment or other relationships, to information about us.

On June 16, 2004, we issued warrants to purchase 47,618 shares of our common stock to six of our stockholders in connection with the repayment of principal outstanding under notes payable held by two of the stockholders. Such warrants have an exercise price equal to \$12.00 per share and expire if not exercised on or before June 16, 2008. The offers, sales and issuances of the warrants were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act because the issuance of warrants to the recipients did not involve a public offering. The recipients of the warrants represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to warrants issued in such transaction. Each of the recipients of the warrants were accredited or sophisticated persons and had adequate access, through employment, business or other relationships, to information about us.

(d) We effected the initial public offering of our common stock pursuant to a Registration Statement on Form S-1 (File No. 333-113760) that was declared effective by the Securities and Exchange Commission on June 9, 2004. On June 15, 2004, 5,500,000 shares of common stock were sold on our behalf at an initial public offering price of \$12.00 per share, for an aggregate offering price of \$66.0 million, which offering was managed by Merrill Lynch, Pierce, Fenner & Smith Incorporated, J.P. Morgan Securities Inc., Banc of America Securities LLC and William Blair & Company, L.L.C. Following the sale of the 5,500,000 shares, the offering terminated.

We paid to the underwriters underwriting discounts and commissions totaling approximately \$4.6 million in connection with the offering. In addition, we estimate that we incurred additional expenses of approximately \$2.6 million in connection with the offering, which when added to the underwriting discounts and commissions paid by us, amounts to total estimated expenses of approximately \$7.2 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and commissions and estimated offering expenses, were approximately \$58.8 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

We expect to use a majority of the net proceeds from our initial public offering to manufacture and market our gamma cameras, build our sales and marketing capabilities, expand our business and repay outstanding lines of credit and notes payable. As of June 30, 2004, we had repaid the approximately \$9.7 million that was outstanding under our lines of credit and notes payable from the net proceeds, none of which was paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

To a lesser extent, we anticipate using the remaining net proceeds of the offering:

for further research and development relating to our existing products and new product opportunities and to finance regulatory approval activities; and

for general corporate purposes.

In addition, we may use a portion of the net proceeds from our initial public offering to acquire products, technologies or businesses that are complementary to our own, but we currently have no commitments or agreements relating to any of these types of transactions.

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We cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of our initial public offering. The amount and timing of our expenditures will depend on several factors, including the amount of revenue generated from our operations, the progress of our commercialization efforts, and the amount of cash used in our operations. Accordingly, our management will have broad discretion in the application of the net proceeds.

Pending the uses described above, we plan to invest the net proceeds from our initial public offering in short- and medium-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Other than the authorized capital stock numbers set forth in our amended and restated certificate of incorporation referenced below, the following share numbers referenced in this Item 4 do not reflect a 1-for-3.5 reverse split of our common stock effected on June 2, 2004.

#### *April 30, 2004 Written Consent Action*

Effective as of April 30, 2004, our stockholders acted by written consent action pursuant to Section 228 of the Delaware General Corporation Law to approve the following matters:

the filing of an amendment to our amended and restated certificate of incorporation to effect a 1-for-3.5 reverse split of our common stock;

the filing of an amended and restated certificate of incorporation, effective upon the closing of our initial public offering, to provide for, among other things, authorized capital stock of 150,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock;

the restatement of our bylaws, effective upon the closing of our initial public offering;

the adoption of our 2004 Stock Incentive Plan, effective upon the closing of our initial public offering;

the adoption of our 2004 Non-Employee Director Option Program, effective upon the closing of our initial public offering; and

the approval of a form of indemnification agreement by and between us and each of our directors and officers.

Stockholders holding an aggregate of 32,120,664 shares approved each of the above matters and stockholders holding approximately 11,638,149 shares did not vote with respect to such matters.

#### *May 17, 2004 Annual Meeting of Stockholders*

On May 17, 2004, we held an annual meeting of stockholders to approve the following matters:

the election of seven directors to our board of directors to serve until the next annual meeting of stockholders; and

the ratification of the appointment of Ernst & Young LLP as our independent public accountants for the fiscal year ending December 31, 2004.

At the time of the meeting of the stockholders, which was held prior to the completion of our initial public offering, the amendment and restatement of our certificate of incorporation and the conversion of all outstanding shares of our preferred stock to common stock, holders of our Series G preferred stock were entitled to elect two members of our board directors, holders of our Series H preferred stock were entitled to elect three members of our board of directors and holders of our preferred stock and common stock, voting together as a single class, were entitled to elect the remaining members of the board.

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At the annual meeting of stockholders, the following directors were elected to our board of directors by holders of our Series G preferred stock, Series H preferred stock and common stock and preferred stock, voting together as a single class, respectively, according to the votes listed below:

*Series G preferred stock:*

Nominee	For	Withheld	Abstaining
Robert M. Jaffe	21,597,152	1,079,262	-0-
Timothy J. Wollaeger	22,753,650	87	-0-

*Series H preferred stock:*

Nominee	For	Withheld	Abstaining
Douglas Reed	8,960,646	87	-0-

*Common Stock and Preferred Stock:*

Nominee	For	Withheld	Abstaining
David M. Sheehan	31,730,102	87	-0-
R. King Nelson	31,730,102	87	-0-
Kenneth E. Olson	31,730,102	87	-0-
Raymond V. Dittamore	31,730,102	87	-0-

Mr. Jaffe submitted his resignation on May 14, 2004, to be effective immediately prior to the effectiveness of our initial public offering.

With respect to the ratification of the appointment of Ernst & Young LLP as our independent public accountants for the fiscal year ending December 31, 2004, holders of shares of our common stock and preferred stock, voting together as a single class, voted as follows:

For	Withheld	Abstaining
30,650,937	1,079,250	2

*May 21, 2004 Written Consent Action*

Effective as of May 21, 2004, holders of shares of our Series H preferred stock acted by written consent action pursuant to Section 228 of the Delaware General Corporation Law to acknowledge and agree that the sale by us of our common stock in a bona fide, firm commitment underwritten public offering registered under the Securities Act, which resulted in (i) aggregate gross offering proceeds of at least \$25,000,000 and (ii) a public offering price which valued us (immediately prior to such offering) at \$169,000,000 or more, would constitute a Qualifying Public Offering under our amended and restated certificate of incorporation.

Holders of an aggregate of 9,911,621 shares of Series H preferred stock approved the foregoing matter and holders of approximately 2,650,085 shares of Series H preferred stock did not vote with respect to such matter.

*May 21, 2004 Written Consent Action*

Effective as of May 21, 2004, our stockholders acted by written consent action pursuant to Section 228 of the Delaware General Corporation Law to approve the following matters:

the amendment of provisions of our restated bylaws to be in effect following the completion of our initial public offering pertaining to the calling of special meetings of stockholders; and

the approval of a correction to our 2004 Non-Employee Director Option Program to be in effect upon the closing of our initial public offering regarding the number of options to be received by our non-employee directors hereunder.

Stockholders holding an aggregate of 30,458,137 shares approved each of the above matters and stockholders holding approximately 13,300,676 shares did not vote with respect to such matters.



**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

(a) Exhibits

Exhibit Number	Description
3.1	Restated Certificate of Incorporation
3.2	Restated Bylaws
4.1(1)	Form of Specimen Stock Certificate
4.2(1)	Amended and Restated Investors Rights Agreement by and among Digirad Corporation and the investors listed on the schedule attached thereto, dated April 23, 2002, as amended.
10.1	Amendment to License Agreement by and between Digirad Corporation and the Regents of the University of California, dated July 26, 2004.
10.2(1)	Loan Agreement by and between Digirad Corporation and Clinton L. Lingren, dated September 1, 1993, as amended.
10.3(1)	Loan Agreement by and between Digirad Corporation and Jack F. Butler, dated September 1, 1993, as amended.
10.4 #	2004 Stock Incentive Plan.
10.5(1) #	2004 Non-Employee Director Option Program.
10.6	Form of Warrant to purchase shares of Common Stock by and among Digirad Corporation and the investors listed on the schedule thereto.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) This exhibit was previously filed as an exhibit to the Registration Statement on Form S-1 (File No. 333-113760) originally filed with the Commission on March 19, 2004, as amended thereafter, and is incorporated herein by reference.

Application has been made to the Securities and Exchange Commission to seek confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

# Indicates management contract or compensatory plan.

(b) Reports on Form 8-K

There were no current reports on Form 8-K filed by Digirad Corporation during the quarter ended June 30, 2004.



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## SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DIGIRAD CORPORATION

Date: August 11, 2004

By: /s/ David M. Sheehan

David M. Sheehan  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 11, 2004

By: /s/ Todd P. Clyde

Todd P. Clyde  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

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